EXHIBIT 44

In Re:

Digitek

Liana Radtke

January 26, 2010

Confidential – Subject to Further Confidentiality Review

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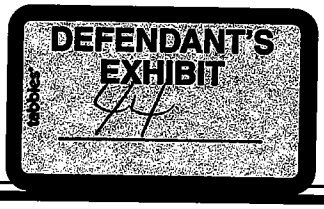

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS: MDL NO.
LIABILITY LITIGATION : 1968

(This document relates to all cases.)

CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

IN THE CIRCUIT COURT OF KANAWHA COUNTY,
WEST VIRGINIA

IN RE: DIGITEK LITIGATION
Civil Action No. 08-C-5555

THIS DOCUMENT APPLIES TO:

Diana L. Adkins v. Mylan Pharmaceuticals, Inc., et al.	No. 09-C-40 KAND
Thomas Beveridge v. Mylan Pharmaceuticals, Inc., et al.	No. 08-C-273 OHI
Carl Brown v. Mylan Pharmaceuticals, Inc., et al.	No. 09-C-123 NIC
Elizabeth Byus v. Mylan Pharmaceuticals, Inc., et al.	No. 08-C-1954 KAN
James R. Christian v. Mylan Pharmaceuticals, Inc., et al.	No. 09-C-292 MON
John Anthony Conte v. Mylan pharmaceuticals, Inc., et al.	No. 08-C-1995 KAN
Martha Florence Guy, POA v. Mylan Pharmaceuticals, Inc., et al.	No. 08-C-303 OHI
Claude E. Jarrell v. Actavis Group, et al.	No. 09-C-512 KAN

(Caption Continued)

THE DEPOSITION OF LIANA RADTKE
JANUARY 26, 2010

Bobbi J. Myers v. Mylan Pharmaceuticals, Inc., et al. — No. 08-C-999 KAN

Melvin L. Pennington, et ux. v. Mylan Pharmaceuticals, Inc., et al. — No. 08-C-172 PNM

Lola Jean Smith, et us. v. Mylan Pharmaceuticals, Inc., et al. — No. 08-C-1069 KAN

Russell A. Wells v. Mylan Pharmaceuticals, Inc., et al. — No. 09-C-003 NIC

The deposition of LIANA RADTKE, called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before JULIANA F. ZAJICEK, CSR No. 84-2604, a Notary Public within and for the County of Kane, State of Illinois, and a Certified Shorthand Reporter of said state, at the offices of Segal McCambridge Singer & Mahoney, Ltd., Suite 5500, 233 South Wacker Drive, Chicago, Illinois, on January 26, 2010, at 9:00 a.m.

PRESENT:

SANFORD BARLOW LLP,
BY: ANTHONY C. COVENY, PH.D., ESQ.
1500 McGowen, Suite 250,
Houston, Texas 77004,
713-524-6677
acoveny@SanfordBarlow.com
Counsel for Plaintiffs and Plaintiffs' Steering Committee

LAW OFFICES OF MICHAEL F. COLEY & ASSOCIATES
BY: MICHAEL F. COLEY, ESQ.
1201 Dove Street, Suite 220,
Newport Beach, California 92660
949-955-0700
m-law@att.net
Counsel for Plaintiff Connie Quinn

TUCKER ELLIS & WEST LLP
BY: EDWARD E. TABER, ESQ.
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1414
216-696-2365
edward.taber@tuckerellis.com
Counsel for Actavis Defendants

SHOOK HARDY & BACON L.L.P.
BY: HARVEY L. KAPLAN, ESQ.
2555 Grand Boulevard
Kansas City, Missouri 64108-2613
816-474-6550
hkaplan@shb.com
Counsel for Mylan Defendants

ALLEN GUTHRIE & THOMAS, PLLC
BY: JAMES S. ARNOLD, ESQ.
500 Lee Street, East, Suite 800
Charleston, West Virginia 25301
304-720-4225
jsarnold@agmtlaw.com
Counsel for West Virginia Actavis Defendants

VIDEOTAPED BY:

MR. ANTHONY MICHELETTO,

Golkow Technologies, Inc.

REPORTED BY: JULIANA F. ZAJICEK, C.S.R.

CERTIFICATE NO. 84-2604.

THE VIDEOGRAPHER: We are now on the record. My name is Anthony Micheletto. I am the videographer for Golkow Technologies.

Today's date is January 26th, 2010. The time is 9:01 a.m. as indicated on the video screen. This video deposition is being held in Chicago, Illinois, in the matter of In Re Digitek Products Liability Litigation for the court of United States District Court for the Southern District of West Virginia. The deponent is Liana Radtke.

Counsel, please introduce yourselves for the video record.

MR. COVENY: I am Tony Coveny representing various Plaintiffs in the MDL.

MR. COLEY: Michael Coley, and I represent the Quinn family.

MR. ARNOLD: Jim Arnold, West Virginia local counsel for all Defendants.

MR. KAPLAN: My name is Harvey Kaplan with Shook, Hardy & Bacon. I represent the Defendant Mylan.

THE VIDEOGRAPHER: The court reporter today is Juliana Zajicek. Please swear in the witness.

(WHEREUPON, the witness was duly

sworn.)

THE VIDEOGRAPHER: You may proceed.

LIANA RADTKE,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. COVENY:

Q. Good morning, Ms. Radtke.

A. Good morning.

Q. And how are you this fine day.

First off, I'd like to ask you, how did you prepare for today's deposition? Who did you speak to and did you review any documents?

A. I -- about two weeks ago I met with Erica Downey to indicate that I would be deposed in a couple of weeks and then yesterday I met with Mr. Kaplan. And, no, I did not review any documents.

Q. Okay. Would you please for the record give us a bit of your education background preparing yourself for the position you currently hold?

A. Okay. I have a bachelor's degree in education. I was an English teacher. And

approximately close to 25 years ago I began my employment at UDL Laboratories and started out in various positions until to the position that I hold today.

Q. Okay. Did you work in the area of pharmacy -- it appears you say -- said no, you did not work in pharmacy before going to UDL?

A. No, no.

Q. Is the primary basis of your current position then work experience?

A. Yes.

Q. Okay. Is there any specialized training to hold the position that you have now, any particular certificates, any particular certifications that are required?

A. No. I belong to RAPS, but --

Q. Which is?

A. Regulatory Affairs Professional Society.

Q. Okay. All right. What positions have you held at UDL prior to your current position?

A. I started out at -- with just the stability program where we were testing and then I worked in government contracts for a short time and then I assumed my position of regulatory affairs

compliance, which is the position I assume today.

Q. Okay. Would you say that that's standard in your experience across the board in the industry, that people that work in regulatory affairs, it's primarily on-the-job training?

A. I really can't respond to that. I don't -- I can't respond to that.

Q. Okay. That's just your personal one?

A. Yes, um-hum.

Q. Okay. All right. If you don't mind, I'm going to take just a moment to go over the relationship between UDL, Mylan. I have right here --

MR. COVENY: And, counsel, I'll provide you with the UDL Laboratory management.

BY MR. COVENY:

Q. This is Mylan 35607, which I believe is already in an exhibit, but for today -- I received a text. I believe we are starting with M42 in terms of exhibits. They weren't quite certain if they were updated, so we are going to go ahead and start with M42 for exhibits, and we'll go ahead and put this in in case it's not in.

I'm going to go ahead and hand you --

A. Okay.

Q. -- Ms. Radtke, the --

MR. COVENY: And other counsel, do you prefer that I put this up on the screen just so you can see what we are referring to? It may have some of my own writing on it, not much, but -- let's see if we can get that into focus. I guess we can read that pretty well.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M42, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Ms. Radtke, you currently work for UDL Laboratories and have for 25 years?

A. It will be 25 years in July, yes.

Q. Okay. Are you an employee of Mylan then?

A. I am an employee of UDL and we are owned by Mylan, Inc.

Q. Okay. I noticed on this one here, do you answer directly to Louis Debone in your -- in your job as federal regulatory affair?

A. No.

Q. Okay. Do you answer to anyone at Mylan

directly or do you stick strictly with UDL?

A. No. I have -- my direct record is to UDL.

Q. Okay. I noticed across from you is Sue Powers, director of quality assurance.

Could you explain to me a little bit about the difference between your job as director of regulatory affairs and compliance and how you understand her job as director of quality assurance?

A. Okay. Sue is in charge of quality insurance receiving, and she is also in charge of quality assurance in process. The validation department reports to her and label control.

Q. Okay. And so she is in charge of making sure that the product is up to standard at all times from the time it's received?

A. Yes.

Q. To the time that you then send it out?

A. Yes.

Q. How does that differ from your job?

A. I -- my particular position we take care of the stability program.

Q. Could you explain that for a moment?

A. Yes. Okay. Before we can market a product, we have to put it in the packaging material that we would commercialize it in. It's sent out for testing per the USP, and it must conform to all of its specifications in order for us to assign an expiration date. And once it's in the line, we have a continuing program to continue to support the expiration date of the product.

Q. Okay. So, both Ms. Powers and yourself are in charge of the process but different aspects of the process?

A. That's correct.

Q. How much of the product is sampled when you say you test it? You receive product obviously from Actavis?

A. We receive this product directly from Mylan and --

Q. Okay.

A. -- under the Mylan label.

Q. Okay. And when you receive -- so, you don't receive any product directly from Actavis?

A. We -- currently? No.

Q. No, no, no. In the past.

A. In the past, we -- this is with regard

to Digitek?

Q. With regard to Digitek.

A. No. We would receive -- we received all of that through Mylan Pharmaceutical.

Q. Okay. So, are you aware of the fact that it went from Actavis to Mylan and then to you?

(WHEREUPON, Mr. Edward E. Taber entered the deposition proceedings.)

BY THE WITNESS:

A. Yes.

BY MR. COVENY:

Q. Was the testing of the product then done at Mylan prior to coming to you or did you continue to test product at UDL?

A. Test it -- could you clarify what you mean by test?

Q. You said that during part of the stability program you would test the product?

A. Well, when you put it into the blister -- in your packaging configuration, you are required to support your expiration date. So we would have -- it was a sample lot that we would send out for testing each year.

MR. COVENY: Just a moment. Mr. Taber?

MR. TABER: Yes.

MR. COVENY: Mr. Taber has just joined us.

BY MR. COVENY:

Q. On page 12 of the document that I handed you --

MR. TABER: Counsel, do you have an extra copy of the exhibits?

MR. COVENY: Just right here and we have -- I've put them up on the screens right here. You can either look on with Mr. Kaplan or we can get you a -- turn a monitor around for you if it would be easier for you.

MR. TABER: Yeah, that would be great, if I could see that as well.

MR. COVENY: Just a moment here. We are going to turn my monitor around since I can see it. We'll see how far this monitor will reach.

(WHEREUPON, there was a short interruption.)

BY MR. COVENY:

Q. Ms. Radtke, then you answer to Vince Mancinelli, is that correct?

A. No.

Q. Okay. According to this on page 12, you are underneath him. Who do you report directly to then?

A. Jodi Eichelberger.

Q. Jodi Eichelberger, okay.

And is she somewhere on this organizational chart that you are aware of? Did you see her on page 1 or --

A. No.

Q. Okay. And do you know what her position then is?

A. She is vice president, general manager of UDL Laboratories.

Q. Okay. All right. So when -- during the time period in question when you were receiving Digitek, it was coming to you from Mylan?

A. Correct.

Q. Your job was packaging it and distributing it?

A. And to distribute those.

Q. You sent samples out to be tested?

A. Yes.

Q. How many samples of each batch would be sent out, do you recall?

A. I can't give you a specific number. I don't have that on the top of my head.

Q. Okay. But every batch was tested?

A. No, not stability testing.

Q. Okay. Okay.

A. Okay.

Q. I'm going to put up another document up here on the screen. This is document 191569. And I am going to give you a copy of it here. This will be Exhibit --

MR. COVENY: 44 or 45 now?

THE COURT REPORTER: 43.

BY MR. COVENY:

Q. -- 43, M43. And, again, I believe this is where they left off of these depositions. They are moving rather quickly in order.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M43, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. This right here is a confidentiality agreement between UDL and Actavis dated 2006.

In your recollection, when is the soonest -- you've been at UDL for 25 years. When

is the -- when did the relationship between UDL and Actavis begin? What is the earliest in your recollection you began receiving product from them?

MR. KAPLAN: Objection; it misstates the witness' early testimony about receiving product. She said they did not receive product from Actavis.

MR. COVENY: Absolutely, okay.

BY MR. COVENY:

Q. Digitek you received from Mylan?

A. Correct.

Q. When is the earliest in your recollection you began receiving Digitek from Mylan that was produced at Actavis?

A. I can't give you the exact year.

Q. Okay.

A. I don't remember the exact year.

Q. That's fine. We'll go through that --

A. Okay.

Q. -- a little bit later in some of the documents.

I'm going to go ahead and pull that one off the screen and put up here -- well, we'll hold off on that.

Are you aware of there being an

indemnity agreement directly between UDL and Actavis at all?

A. I'm not certain.

Q. That's fine. Okay. That would be...

During the recall, I'll go ahead and put this up here, this is an e-mail and we'll mark this as Exhibit 44 then 202701.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M44, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. This e-mail is from Sue Powers and you are copied on it. In the second -- at the top of the page, halfway through the first e-mail, it says, "FYI - UDL has received some reimbursement for the total cost listed for the Actavis recalls."

In your recollection, was UDL being reimbursed for their recall activities during the recall up to the present? Were they receiving reimbursement directly from Actavis for those procedures?

A. I'm not sure. I'm not certain.

Q. Okay. This e-mail does that refresh your memory at all? Do you remember who you were

receiving reimbursement from? Was it coming from Mylan?

A. No, I -- that's not my area of responsibility, so I'm uncertain.

Q. Okay. And who is Chuck Koon?

A. Chuck Koon is in the quality assurance department in Mylan Pharmaceutical.

Q. Okay. All right. We'll set that one aside.

Could you tell me what a consent decree is?

A. As I understand a consent decree, it's something that a company enters into with the FDA.

Q. Okay.

A. Certain conditions in which I'm not sure what the particulars would be, but that's my understanding, it's an agreement between the FDA and manufacturing -- or a firm.

Q. And it's -- is it fair to say that a company would not want to be under a consent decree?

MR. KAPLAN: Objection. It calls for hearsay.

MR. TABER: Objection.

BY MR. COVENY:

Q. Okay. Is a consent decree given following violations of some sort, the FDA finding some violations of some sort?

MR. KAPLAN: Objection; lacks foundation.

MR. COVENY: Okay. All right.

BY MR. COVENY:

Q. Are you aware that Amide Pharmaceuticals, thereafter Actavis Pharmaceuticals, was operating under a consent decree for a period of time?

A. I don't recollect that.

Q. Okay. Well, we'll come up with some documents --

A. Okay.

Q. -- that probably will refresh your memory in a moment.

Let's go to what is a Quality Systems Improvement Plan, a QSIP, are you familiar?

A. That would -- again, that is something that would be submitted to the FDA. Exactly what it says. It's a quality system improvement plan. Other than that I don't -- I can't give you any specifics.

Q. Is there a difference in your

understanding between a consent decree and a quality system improvement plan? Is one more serious than the other?

A. In my -- I believe that you would have a quality system improvement plan first. I'm -- I would be uncertain as to when a consent decree would be issued. I don't know.

Q. Has -- has UDL Laboratories in your tenure there as -- let me see your official title -- you're in charge of FDA compliance, ever operated under an concept decree?

A. No, we have not.

Q. Have you ever been subject to a quality system improvement plan?

A. No.

Q. You have not, okay.

And how long at UDL would -- and is that true your entire time at UDL or only during your tenure in your current position?

A. I can only speak to -- to my tenure, and I would say that that is.

Q. All right. In your -- to your knowledge, is there a supply and distribution agreement directly between UDL and Actavis?

A. I don't believe so.

Q. Okay. So your relationship -- in your understanding, your relationship was with Mylan and Mylan has --

A. Correct.

Q. Its -- okay. Its agreement with Actavis. All right.

This next document I'm going to go ahead and pop up here. This next document here is a memorandum from yourself dated January 21st, 2008, and we'll go ahead and put this in as 45. It's document No. 25489. Here you are and here you are.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M45, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. What is an F -- what is FOI?

A. Freedom of information.

Q. Okay. And according to this memo here regarding Actavis, on the background information it states, "Actavis Totowa has been approved by the UDL as a supplier of pharmaceutical drug products since 2004 when the company operated as Amide Pharmaceuticals." UDL currently purchases three

products. Digitek is the one named.

Down here it says under FOI request, "Additional information must be obtained through FOI. The last review of available information was performed on January 21, 2008. It was verified that the information we currently have on file is more currently that -- than that -- than what is available through this service."

MR. TABER: I'll just object to the reading as you are not reading that correctly, but go ahead.

MR. COVENY: At least to holding. Thank you.

BY MR. COVENY:

Q. All right. On this one here, what service do you use to obtain your information?

A. Typically we use the FOI service, the freedom of information.

Q. Okay. And yet your information on file was more current than theirs?

What other source do you use for your information?

A. If -- if the supplier were to provide us information, well, that would be the only other way we would be able to obtain information if they would release it to us.

Q. Does Mylan provide you periodic updates of third-party suppliers?

A. Only if we were to request that through Mylan.

Q. Okay. Do you -- do you directly consider -- is UDL a third-party supplier to -- excuse me. Is Actavis a third-party supplier to UDL?

A. Currently?

Q. Well, during this time, was it a third-party supplier to you? Did you consider that a third-party supplier or were you simply getting the product from Mylan and they were a third-party supplier to Mylan?

A. As it, well, applies to Digitek, we would have gotten the product through Mylan.

Q. Did UDL ever perform an inspection of Actavis itself, of its plant, of its processing procedures?

A. I don't recall.

MR. KAPLAN: Tony, just for the record, a number of documents that you are putting up have highlighting on them, and just for the record that highlighting is your highlighting and not the

witness' highlighting?

MR. COVENY: That is correct, it is mine.

MR. KAPLAN: Okay.

BY MR. COVENY:

Q. Can you tell me how often the DEA performs inspections of UDL?

A. The DEA, drug enforcement?

Q. Yeah. I'm going to go ahead and put this up here. This is a Notice of Inspection of Controlled Premises. This is the document here.

A. It's a --

(WHEREUPON, a certain document was marked Deposition Exhibit No. M46, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Just very quickly for the record, this would be Exhibit M46, document No. 20672. We have here the document.

Would you tell me what this document is?

A. This is a Notice of Inspection when the DEA comes to your facility to perform its inspection.

Q. How does this differ from an FDA inspection?

A. The DEA only deals directly with controlled substances or list one chemicals. So, if you have a license to process controlled substances or list one chemicals, you have to have a DEA license, and they -- they have the right and obligation to come in and inspect you periodically.

Q. Okay. Do you know how often they come in to perform inspections?

A. Typically it's every three to four years.

Q. Every three to four years, okay.

How does it differ from an FDA inspection?

A. The DEA looks for signs of diversion. I would say that that is probably their -- their main performance. They also check your -- make sure that your security is in line with the controlled substances. There are certain provisions that you must meet. So, that's -- that's usually their focus.

Q. Okay. All right. Then let's move to FDA inspections. How often does the FDA inspect a pharmaceutical manufacturer --

A. They typically --

Q. -- distributor?
A. -- come in every three years.
Q. Every three years?
A. Um-hum.
Q. And how many inspections have you gone through -- or in your -- in your current position would you be the point person when the FDA comes in?
A. Correct. I can't give you the exact number of inspections.
Q. Understood. But approximately every three years?
A. Approximately every three years.
Q. Okay. All right. I'm going to put an e-mail up here. We'll do this as M46.
THE COURT REPORTER: 47.
BY MR. COVENY:
Q. 47, M47. This is an e-mail from yourself and then a chain with Sue Powers listed as well. Here is the e-mail. Here you are.
(WHEREUPON, a certain document was marked Deposition Exhibit No. M47, for identification, as of 1/26/10.)
BY MR. COVENY:

Q. On the second page there, it looks like an e-mail from Sue Powers to Chuck. And, yes, the highlighting is mine on this copy here.

The e-mail indicates that many of the suppliers have not been audited.

In your time at UDL, did you -- you said you were not familiar with whether or not UDL -- or you could not recall whether or not UDL had ever audited Actavis directly.

Were you in charge of auditing any other pharmaceutical distributors or manufacturers?

A. I would -- I can't recall at what point in -- you know, in my tenure that I started participating in supplier audits. I really don't remember the year. I wouldn't have done that right, you know, immediately. I just don't remember the year that I would have participated in that type of audit of a supplier.

Q. In your recollection, how many have you done of on-site inspections of manufacturers or producers?

A. Maybe four or five at the -- I really don't know the exact number.

Q. Okay. And you do not recall whether you

ever went to Actavis?

A. I'm uncertain on that.

Q. Is this mandated by -- under -- does the FDA have a requirement that you audit third-party suppliers?

A. There is nothing in the Code of Federal Regulations that requires you to audit your suppliers.

Q. Okay. Do you have a standard operating procedure at UDL that indicates that you should perform these audits?

A. We have a vendor assessment program that's undergoing some changes right now through global quality, but it would be to monitor the activities, the compliance history of your -- the companies that you're -- you're purchasing from.

Q. When you say monitor the compliance history, does that require an on-site inspection or is that more akin to a document review?

A. It's not -- if you're asking -- are you asking if it's a requirement in the -- within the --

Q. No, no. When you do a compliance review of a third-party vendor, are you going to that

third-party vendor and actually reviewing their -- their site and their production?

A. No, not necessarily. No, uhn-uhn.

Q. Okay. Would it consist of reviewing documents pertaining to the FDA?

A. Yes. We would get freedom of information, we would access the FDA website to see if there was any type of information that would be available.

Q. Okay. Would it be fair to say that a third-party vendor usually notifies you of a violation prior to you finding out about it from the FDA directly?

MR. TABER: Objection.

BY MR. COVENY:

Q. Have you ever found out about an FDA violation directly from the FDA without having been notified by the vendor itself?

A. From -- through the FDA?

Q. From a review of say the FDA web page like you said or through the review of the FDA documents.

A. Could you -- okay. Could you rephrase your question?

Q. Absolutely.

A. Okay.

Q. When a third-party vendor or one of your suppliers is given a warning letter or a QSIP or operating under a consent decree, do they have to notify you directly?

MR. TABER: Objection.

BY MR. COVENY:

Q. Have you been notified directly from third-party vendors when those situations take place?

MR. KAPLAN: Objection; vague, general, lacks specificity.

BY MR. COVENY:

Q. All right. We'll go -- we'll come back to that question. I have some documents.

This next document then will be M48. It begins with document 203166.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M48, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Do you recall when the most current FDA inspection of UDLs took place?

A. Yes. August of 2008.
Q. And it is fair to say that that was the standard three-year --
A. Yes.
Q. -- inspection from the FDA?
A. Yes, correct.
MR. TABER: Just note my objection to the phrase "standard." I think that's your phrase and not hers and not the FDA's.
BY MR. COVENY:
Q. All right. It was a scheduled inspection from the FDA?
A. FDA does not schedule our inspections. They just arrive. So, this was just a -- their inspection of UDL.
Q. What is a 483?
A. That is actually referencing the form that the FDA would use that would put -- they would put down observations if they were to find something during an inspection that you may have to explain further.
Q. Okay. During this recent inspection of UDL, did UDL receive any 483s?
A. No, we did not.

Q. Could you tell me what a change control is?

A. We have various change controls. This would -- it would just depend on what change control we were talking about. Could you be a little bit more specific?

Q. Yes. On page 4 of that document, in the middle of the last large paragraph there, it says, "These issues were addressed in a change control which was presented to the inspector prior to the closeout of inspection."

A. Without knowing what the specific change control is, I don't think I can respond to your question.

Q. Okay.

MR. TABER: Sorry. Is that your writing in the margin?

MR. COVENY: This is my writing, yes. I did not anticipate putting them up on here. I was just going to hand copies, so I wrote on my originals.

MR. KAPLAN: And I'm going to object to the relevancy. This has nothing to do with Digitek.

BY MR. COVENY:

Q. Okay. Would you consider it to have

been a successful inspection?

A. Yes.

Q. Okay. In your opinion then, UDL has complied with all FDA regulations during your tenure there?

MR. KAPLAN: I'm going to object. This calls for opinion testimony from a fact witness. She is not an expert.

BY MR. COVENY:

Q. Okay. But it is fair to say that you've received no 483s and no QSIPs during your -- at least in the last inspection?

A. Yes, that's correct, we have not.

Q. Your job is FDA compliance. Does the FDA require a person hold that position at UDL?

A. Excuse me. I --

Q. Let me rephrase that.

A. Yes, please.

Q. The FDA has many, many requirements on pharmaceutical manufacturers and distributors. How important is having that position, of having FDA compliance at UDL?

A. Oh, it's very important to be a compliant firm. Are you asking me specifically of

my -- my --

Q. Obviously as a pharmaceutical company you produce a lot of products that are going to be consumed by individuals. Is compliance with FDA regulations important for their safety?

MR. KAPLAN: Objection. First of all, UDL does not produce any products. They distribute products.

MR. COVENY: Certainly distribute.

MR. KAPLAN: Yeah, and it calls for hearsay.

BY MR. COVENY:

Q. Would you consider your position an important position?

A. Yes, I do.

Q. Would you consider compliance with FDA regulations important?

A. Yes, I do.

Q. Based on what? Why is it important -- why is it important that UDL comply with FDA regulations?

A. We have certain responsibilities for the safety of the product that we are producing.

Q. In this case distributing?

A. Distributing. I said producing.

Distributing, yes.

Q. Would you say that compliance with FDA regulations is indicative of quality product or quality distribution?

MR. TABER: Objection.

MR. KAPLAN: Overbroad, lacks specificity, calls for hearsay.

BY MR. COVENY:

Q. We don't need to go any further on that. I just want to give you one document before we leave the FDA inspection of UDL.

A. Okay.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M49, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Are you familiar with this document? This will be M49, document No. 202712.

A. I'd have to review the entire document.

Q. Okay.

MR. KAPLAN: Go ahead and take your time to do it.

BY THE WITNESS:

A. I believe this was -- this is a

spreadsheet that the quality assurance department issued.

BY MR. COVENY:

Q. Do you know who Melinda Brazer is?

A. Yes. She is the administrative assistant for Sue Powers.

Q. Okay. And is it your understanding that this was produced in response to the FDA inspection in 2008?

A. Yes, that's my understanding.

Q. Okay. Just one question. On page No. 4 -- and, again, those of you looking at it, on the document monitor, the writing is mine -- No. 76.

A. Okay.

Q. It says, "Not enough QA checks in phases of validation."

Is it your understanding that the FDA wanted additional quality assurance checks during the validation process?

MR. KAPLAN: I'm going to object. This has nothing to do with Digitek.

MR. COVENY: We'll go ahead and put that one down.

BY MR. COVENY:

Q. So, in addition to DEA and FDA inspections, Mylan Pharmaceuticals periodically does -- conducts an audit of its third-party vendors. Let me go ahead and provide you with this document. This will be M48, document 30303.

THE COURT REPORTER: It is 50.

MR. KAPLAN: This would be 50.

MR. COVENY: 50. Thank you.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M50, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Take a moment to look that over.

On page 2 of 3 -- tell me when you are -- when you feel comfortable looking at this document there.

A. Okay.

Q. Okay. On the bottom of page 2 of 3 in the paragraph beginning, "Amide Pharmaceuticals was acquired by Actavis in July 2005."

A. Okay.

Q. Would you mind reading the very last line?

A. "A shortage of qualified" --

MR. KAPLAN: I am going to object to the relevancy. This has nothing to do with the UDL and it has nothing to do with Digitek.

BY MR. COVENY:

Q. Okay. This -- Mylan's inspection of Actavis, is it fair to say from this document that they found there to be a shortage of qualified individuals, key individuals at Actavis?

MR. TABER: I'll just object to the hearsay. Are you asking her if she knows in her personal knowledge or if -- you are asking her solely to interpret the document? I think the latter is also objectionable.

BY MR. COVENY:

Q. In your personal knowledge, was Actavis operating with a lack of qualified individuals?

MR. TABER: Objection.

MR. KAPLAN: When, for what purpose?

BY MR. COVENY:

Q. Were you familiar with this review --

A. This document?

Q. -- of Actavis from Mylan?

A. No. This is the first time I've ever

seen this document.

Q. Okay. So you -- you were not privy then at any time to Mylan's inspection of Actavis itself?

A. I don't recall seeing this document.

MR. KAPLAN: And just for the record, you've got two different documents here. You start with a document dated January 23, 2008, and then you flip over to --

THE WITNESS: November 2006.

MR. KAPLAN: Well, November 2006 and then December of 2006 is the document that you were referring to on page 2 of 3. So, just for the record.

BY MR. COVENY:

Q. Were you aware at any time of Mylan performing an independent inspection of Actavis?

MR. COLEY: This is Michael Coley speaking.

Counsel, do you have an extra hand copy of Exhibit 50?

MR. COVENY: I'll give you mine.

MR. COLEY: Thank you.

BY THE WITNESS:

A. Could you rephrase your question?

BY MR. COVENY:

Q. I'll withdraw the question.

A. Oh, withdraw it. Okay.

Q. Would you agree that high quality assurance standards are necessary at a pharmaceutical manufacturer or distributor?

A. Yes.

Q. Can you tell me what an assay result is? A-s-s-a-y.

A. A-s-s-a-y?

Q. Yes.

A. Okay. That would be where you are testing the product for potency.

Q. Would you agree that it is important to have strict standards for assay results?

MR. KAPLAN: Objection; vague, indefinite as to what is meant by "strict standards."

BY MR. COVENY:

Q. Do you know what the assay result UDL perimeter limit is for Digitek?

A. I can't -- I can't tell you what the exact parameter limit is for Digitek or was for Digitek.

Q. Okay. This would be 51 then,

Exhibit 51, document 7647.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M51, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. And on this document here -- here you are. And, counsel, I will hand you my copy momentarily. I want to -- it's a rather long document.

If you could turn to page No. 5, the Actavis Certificate of Analysis, and I'll put this up here for everyone to see.

MR. KAPLAN: Can we see what this document is?

MR. COVENY: Absolutely. This is the UDL Laboratories, Inc. Receiving Form.

MR. KAPLAN: Is there a date on the document?

MR. COVENY: 4/10/2008, received from Amide/Bertek/Mylan.

MR. KAPLAN: Is that your writing on it?

MR. COVENY: This right here No. 1 and 2 is my writing, the handwriting, the marginalia is mine.

BY MR. COVENY:

Q. On Page 5 --

MR. KAPLAN: Did you say you have an extra

copy of that?

MR. COVENY: I'll hand you this one momentarily. I have two of this one here. The next two documents are rather lengthy.

MR. KAPLAN: All right.

MR. COVENY: I'll hand it to you momentarily.

BY MR. COVENY:

Q. That is a Certificate of Analysis?

A. Okay. I want to make sure I'm on the same page. Did you say 5, page 5?

Q. Page 5 at the top. It is page 5. This would be -- the Bates number down in the corner would be 7649.

A. Oh, this one. It says page 5 at the top.

Q. Absolutely.

A. Correct, I have it.

Q. Can you tell me what the assay range is for this Certificate of Analysis?

A. It is 90 percent to 105.

Q. Okay. And this particular batch, what was its assay result?

A. 97.4.

Q. Okay. If you move now down to -- it

will be Bates No. 7656. Can you tell me what this is?

A. Okay. This -- this -- our parameter limits are tighter than the specifications. And so this particular product was slightly below our parameter limits.

Q. Could you tell me how your parameter limits are determined?

A. We base them on stability results and product -- we track the product history of the particular product. So we establish tighter limits than what the requirements are.

Q. And who establishes the requirements?

A. This particular -- this is by the USP or it -- the ANDA requirements, but this is a USP product. So, the 90 to 105, that is the USP cry -- it has to meet between -- it has to be within that range to meet the labeled claim.

Q. And yet you have a tighter limit you said for stability reasons?

A. No. It's just internal purposes we've established tighter limits.

Q. And why would you have a tighter limit than the USP?

A. Well, we would -- we do track through the stability program. That's not to say that the 97.4 -- it would still meet the specifications of the product. It still is very well within the specifications.

MR. KAPLAN: The USP?

BY THE WITNESS:

A. The USP specifications for the product. This is a -- this is a self-imposed process that we've put in place.

BY MR. COVENY:

Q. Why would you have a self-imposed process that's tighter than the USP?

A. I'm not sure -- I'm not sure how to respond to that -- that question.

Q. Okay. Would there be any justification or any reason why you would feel that you would need a tighter specification than the USP?

A. No. There -- I mean, we would be allowed -- as long as it's within its specification, we would be allowed to bring it in and repackage it. This is something that we have established tighter limits for the products. That's just a self-imposed process that we put in

place.

Q. Okay. Is there any particular reason why you simply don't adopt the USP?

A. No.

Q. I am going to forward to -- it will be Bates No. 7682.

A. This is another C of A.

MR. KAPLAN: Is this all part of one document or are we --

THE WITNESS: No. This is --

MR. COVENY: These were all -- the way they were produced, it was just contiguous document numbers. This will be another receiving -- a receiving form similar to the first one.

BY THE WITNESS:

A. This is a different -- a different lot number. I'm wondering if this is --

BY MR. COVENY:

Q. Yeah, this one here will be a different lot number with a different assay.

A. I'm still not finding that in here.

MR. KAPLAN: And I don't have it in front of me. I don't know, but I see at the bottom here this has a date of 12/23/07. Is that right?

MR. COVENY: That is correct.
BY MR. COVENY:
Q. At the bottom corner, the 7682 is the Bates number.
A. I have it.
Q. Okay. Again, what is the assay limit on this Certificate of Analysis from Actavis?
A. It is 90 percent to 105.
Q. And the result was?
A. 96.6.
Q. Okay. And, again, was this -- was that acceptable at UDL for distribution?
A. It -- it meets its -- it meets the requirements. It meets its internal -- or the specifications for assay.
MR. KAPLAN: Of the USP?
BY THE WITNESS:
A. Of the USP.
BY MR. COVENY:
Q. And so on document No. 7694, referring to the same lot number, then on 1/9 of '08 you approved this for distribution?
A. Correct.
(WHEREUPON, discussion was had

off the stenographic record.)

MR. COVENY: Counsel, here is that, and I will go ahead and give you.

MR. KAPLAN: Can we have an agreement that any and all highlighting or your notations on these exhibits for the attachment to the deposition will be redacted?

MR. COVENY: Yes.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M52, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. All right. The next document here, this will be No. 52, document 14256.

Could you tell me what this is?

A. This would have been a summary of 483s or a warning letter that I had -- I had done.

Q. Okay. Is this -- so this is regarding a warning letter summary for Actavis? The "Re" at the top.

A. Correct.

Q. On page 1 there, No. 1, the "Firm failed to validate analytical testing method for API."

What is API?

A. Active pharmaceutical ingredient.

MR. TABER: Before you continue to ask your questions, I don't want to interrupt each time, but much of this I know has nothing to do with Digitek, so I'm going to object and ask that as you read various portions of this I be given a continuing objection to anything that has nothing to do with Digitek. Is that fair?

MR. COVENY: That would be fair. And I believe most of that has been redacted -- some has been. Okay.

BY MR. COVENY:

Q. The first one, "4 Point 483, 12/8/99. No 1, Firm failed to validate analytical testing method for API."

Is that a serious accusation?

MR. TABER: Objection.

MR. KAPLAN: Objection; calls for characterization, hearsay.

BY MR. COVENY:

Q. Have you ever received a similar 483 at UDL?

A. We don't manufacture products, so we don't deal with active pharmaceutical ingredient.

Q. Okay. How important is hardness, thickness and the blend on a product that's going to be shipped by UDL?

MR. KAPLAN: Objection; it calls for a hypothetical.

BY MR. COVENY:

Q. Well, as director of FDA compliance, is thickness, hardness and blend part of FDA requirements?

A. For the releasing of the product?

Q. Yes.

A. The manufacturer must meet all of its required specifications in order to release a product. Yes, it's important.

Q. And why would it be important that the hardness, thickness or blend be up to FDA standards?

A. Product must meet its -- the specifications within its -- the approved application.

MR. KAPLAN: And I'm also going to ask for a continuing objection here because I don't think any of this has to do with Digitek specifically.

BY MR. COVENY:

Q. What is a master batch record?

A. A master batch record, are you asking me if a master batch record as I understand it within our operation?

Q. Yes, that would be correct.

A. Okay. A master batch record would be all of the product and all of the packaging materials that would be necessary to create our unit dose package.

Q. Turning the page, at the very top of the page in your summary of 1 Point 483 on 11/29/01, UDL, it says, "No assurance that thin tablets are rejected."

Do you test the product for a tablet thickness at UDL?

A. During the receiving inspection a sampling of the product is taken where they -- we measure to ensure that it meets our tooling requirements. We have tighter specifications for the -- for the tooling of -- that forms our blister.

Q. Okay. You have tighter specifications for that than does Actavis?

A. Our -- are you asking me if our

specifications are tighter?

Q. Yeah, I -- I understand that that's what you said that your specifications are tighter than those received by your suppliers.

MR. KAPLAN: I don't mean to interrupt you, but if you just explain --

THE WITNESS: What the tooling --

MR. KAPLAN: -- the blister pack and what the tooling --

THE WITNESS: Right.

MR. KAPLAN: -- is and all of that --

THE WITNESS: Right.

MR. KAPLAN: -- so you can put that into context for him.

BY THE WITNESS:

A. When we -- when we create a tool for the product, it's based on the sampling of it so that we can get a custom fit blister. So --

MR. KAPLAN: He hasn't gone into blister pack. He doesn't know what UDL does. He might -- you might explain how you distribute the product.

BY THE WITNESS:

A. Okay. What we do is we put it into unit dose so it has a blister which is like -- in this

case clear PVDC and then it has got the peelable lidding, various packaging configurations. So, when we measure the product, it's in order to make sure that the form die that creates the blister that will -- the product will go into that it is -- it's going to be tighter so that you can't get two pills in there and you can't damage the product.

BY MR. COVENY:

Q. So you test for -- you test product size for packaging but not necessarily for the dosage or the strength?

A. Incoming we just -- that would be what we would do is just examine the product for the size.

Q. Is it important to have quality equipment at your -- at the pharmaceutical companies that produce the product for you?

A. You are going to need to specify what quality equipment.

Q. Does the FDA require that certain equipment or that certain equipment be certified or that it be up to specifications for production?

A. The FDA requires that you have quality system checks in place and then the firm has to

determine the equipment that will be utilized to ensure that it's meeting its specifications.

Q. And equipment that was not up to specification would be dangerous?

MR. TABER: Objection.

MR. KAPLAN: It calls for speculation.

BY MR. COVENY:

Q. Okay. Would equipment that was not up to specification, would that be a problem for the FDA?

MR. KAPLAN: Objection; speculation.

BY MR. COVENY:

Q. Would that they consider that a violation?

MR. KAPLAN: It calls for speculation.

BY MR. COVENY:

Q. Has the equipment at UDL been inspected by the FDA?

A. Not -- inspected during -- it would be inspected -- as far as an inspection goes, they may look at the equipment that you are using, but I don't recall any specific equipment.

Q. Has the FDA ever cited UDL during your tenure in your current position for having

equipment that was antiquated?

A. I don't believe so. I don't --

Q. Have they ever cited UDL during your tenure in your current position for equipment that was faulty or failed to meet specifications?

A. I -- I don't recall -- I really -- in my best recollection I would say no.

Q. Okay. Have you ever been faulted for equipment that was improperly cleaned or -- well, any equipment that -- have you ever been cited for any equipment that was improperly cleaned?

A. I -- I don't -- I don't recall.

Q. Have you ever been cited by the FDA for any equipment malfunctions or problems that you are aware of during your tenure in your current position?

A. I'm not aware of any.

Q. Okay. Would it be of concern to you if the FDA were to cite you for equipment that was faulty or in violation in some way?

MR. KAPLAN: Objection.

BY MR. COVENY:

Q. In your current position, are you pleased that during -- after the last FDA

inspection there were no citations given to UDL?

A. Yes, yes, um-hum.

Q. When you wrote this memo, were you surprised at the number of 483s received by Actavis?

MR. TABER: Objection.

BY MR. COVENY:

Q. Okay. Would you consider the results of the FDA inspection of Actavis to be concerning or to be -- let me rephrase that.

Why did you write this memo concerning the 483 warning letters summary for Actavis?

A. This is one of my responsibilities is to -- is to monitor the GMP compliance of any company that we purchase product from. So, this would have just been one of the -- one of my responsibilities to communicate to management if there was anything that I was able to obtain through freedom of information or through the FDA website or whatever source.

Q. And why did you produce this document then going back to 1999? What facilitated your going and producing this document?

A. I don't remember the exact reason why I

would have produced this document.

Q. Is it fair to say that you were concerned about Actavis, the product being produced?

A. No.

MR. KAPLAN: Which product being produced?

BY THE WITNESS:

A. Which product? Digitek?

BY MR. COVENY:

Q. Digitek, specifically Digitek.

A. I was confident in our processes and procedures that we have in place to ensure that we were distributing product that met its specification.

Q. Absolutely. But in producing this document, were you concerned at all about the compliance history of Actavis in your role as a firm that distributes their product?

A. I would say that there -- yes, I would say that there -- in reading this, I would say that there is -- there was concern, yes.

Q. Okay. And is it fair to say that that concern, looking at this document, went back to December of 1999?

A. That I can't really respond to.

Q. But it's your understanding that that is the first -- the first time in your understanding that the FDA issued a 483 to Actavis at least during its relationship concerning Digitek with UDL?

MR. TABER: Objection.

MR. KAPLAN: Objection as to relevancy. There is no indication that 483 had anything to do with Digitek in 1999.

MR. COVENY: Okay.

BY MR. COVENY:

Q. Have you written memorandum like this concerning other third-party suppliers?

A. Yes.

Q. Have there been other third-party suppliers where you found this many FDA warnings and/or issuances of 483s?

MR. KAPLAN: Objection as to relevancy.

BY MR. COVENY:

Q. Okay. Would you consider this an -- let me rephrase that.

When you wrote this memorandum, did this stand out as being a memorandum with an unusual

number of 483s?

MR. KAPLAN: Objection as to the characterization.

BY MR. COVENY:

Q. If you'd go to page No. 5, under that 15 Point 483 on 8/10/06.

A. Is that page 14260?

Q. It would be page 5 at the bottom.

A. Okay. I have it.

Q. No. 14260 Bates number.

A. Okay.

Q. And would you read the first line of point No. 1?

MR. KAPLAN: Objection as to relevancy.

BY MR. COVENY:

Q. Would you say that it is important for the quality control unit to have authority to fully investigate errors that have occurred at a pharmaceutical manufacturer?

A. Yes.

Q. Would you say that a citation by the FDA that that is not the case would be worrisome?

MR. KAPLAN: Objection; calls for speculation and as to relevancy.

BY MR. COVENY:

Q. Why would the QC need authority to fully investigate errors at a pharmacy manufacturer?

A. I don't have enough specifics here to comment one way or another to your --

Q. Just in general?

A. In general?

Q. The quality control department, why should they be given full authority to investigate errors that occur?

MR. KAPLAN: Objection; calls for speculation.

BY MR. COVENY:

Q. The FDA has clearly indicated that a quality control unit should be allowed the full authority to investigate errors. Why do you think the FDA would require that?

A. The quality assurance department would be responsible for releasing a batch into commercial distribution.

Q. Does your quality control unit at UDL have full authority to investigate errors?

A. We don't have a quality control unit. We don't have a laboratory.

Q. Okay. If there is an error at UDL, who

does your investigation?

A. Quality assurance.

Q. Quality assurance. And do they have full authority to investigate all errors?

A. Yes, yes.

Q. Why is that important?

A. It's important because we have to ensure that our product is meeting the specifications to release it into commercial distribution within our control.

Q. Is it fair to say on this, going back to this same document, that the FDA is indicating that at Actavis the QC unit did lack full authority to investigate errors?

A. Again --

MR. TABER: Just note my objection because you are not reading that verbatim. You are paraphrasing.

BY MR. COVENY:

Q. This will be 53. This is an e-mail. In fact, if you could just look at this document. This is an e-mail from yourself to Chuck Koon, again, who I believe you stated on the record was with Mylan.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M53, for identification, as of 1/26/10.)

MR. KAPLAN: Can we have a date on that?

MR. COVENY: It is October 13, 2006.

BY MR. COVENY:

Q. You wrote this e-mail to Chuck Koon in response to the FDA inspection in 2006 of Actavis, is that correct, or Amide?

A. Excuse me. Rephrase that.

Q. Did you -- go ahead and give me the context of this e-mail. You wrote -- you wrote this in response to the Amide warning letter?

A. This would have been my contacting Chuck Koon to -- it was a continuing of monitoring the situation.

Q. At this time had you read the Amide warning letter?

A. Without seeing the actual warning letter, I can't respond to that.

Q. Okay. Who was -- who is Jasmine Shaw?

A. Jasmine Shaw, as I remember, was in charge of regulatory affairs at Actavis.

Q. Okay. And according to this e-mail, it

looks like Jasmine Shaw and Actavis had received a warning letter and they were preparing a response to that warning letter.

Did you receive that response?

A. No.

Q. Okay. It looks, if you go down that page, Chuck Koon had sent you an e-mail prior to your response to him indicating in the second paragraph that Amide was slow to respond to concerns.

Did you have direct contact with Actavis during our following the issuance of the warning letter in 2006?

A. Did we have direct contact?

Q. Did you have direct contact with Actavis?

A. Everything that went through went through Mylan. The only thing I recall is at the one point speaking to Jasmine Shaw. But no, we didn't contact them directly.

Q. Okay. Is it fair to characterize that Chuck Koon said it was difficult to get Actavis to respond to their inquiries concerning the warning letter?

MR. TABER: I'll just object because the document speaks for itself.

BY MR. COVENY:

Q. So you never requested copies of the warning letter from Actavis directly in your recollection?

A. Well, according to this document, I requested it, but I was told that I couldn't get them. And I was given some assurance that the plan that they had in place with the FDA was found acceptable, but they would not release the document to me.

Q. Do you have agreements with any of your third-party vendors to provide copies of warning letters or -- from the FDA -- from FDA inspections?

MR. KAPLAN: You know, I think we established earlier that Actavis is not a third-party vendor of UDL, that UDL purchased all of its product from Mylan.

MR. COVENY: Okay.

BY MR. COVENY:

Q. So and -- so, you may not be able to answer this. I'll just drop that question. Okay.

MR. TABER: Is this a good time for a break?

MR. COVENY: Yeah, this is a good time for a break.

MR. TABER: Okay.

THE VIDEOGRAPHER: We are off the record at 10:13 a.m.

(WHEREUPON, a recess was had from 10:13 to 10:31 a.m.)

THE VIDEOGRAPHER: We are back on record at 10:31 a.m.

BY MR. COVENY:

Q. All right. Ms. Radtke, I'm going to go ahead and put that e-mail on the projector here. Here is a copy for you and counsel.

A. Thank you.

MR. COVENY: Just a moment, counsel, because that's not the same one. Give me just a second here to find the same -- all right. It looks like on this -- on this particular document I only have two copies of it. It is a short one.

BY THE WITNESS:

A. Actually, there is two -- they are both identical.

BY MR. COVENY:

Q. That's why.

MR. KAPLAN: Yeah, why don't you tear that off.

MR. COVENY: Excellent. Thank you.

MR. KAPLAN: All right. So that's 54.

MR. COVENY: That would explain the duplicate copy. Okay. Give me just a moment here to get page 1 and 2. It looks like it was stapled incorrectly.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M54, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. All right. In front of you you have what we'll go ahead and put in as Exhibit No. 54, document 997539. This is your response to Mr. Chuck Koon, dated December 13, 2006.

Now, on the monitor here I have the precipitating e-mail to which he responded in that one. I'm going to go ahead and hand this one to you and give you the full one. If I can have that one back here.

A. Oh, sure.

Q. Your second page didn't print, so there it is. The second page there. Unfortunately we

only have the response.

Could you simply then for the record read your response to Mr. Koon, right, your e-mail to Mr. Koon and tell us the date and the time in which it was sent?

MR. KAPLAN: Is there a second page?

THE WITNESS: Yeah, right here. You don't have it. Do you want to see it?

MR. COVENY: Just a moment.

THE WITNESS: That would have been my e-mail to Chuck.

MR. KAPLAN: Oh, okay. I gotcha.

MR. COVENY: Here is a copy of it. Here it is. It was in a separate e-mail. Okay. Let me go ahead and put it up here on the screen for everyone.

BY THE WITNESS:

A. You are asking me to read?

BY MR. COVENY:

Q. Yes, could you just read that brief e-mail to him.

A. Yes. "Hope all is well with you and the family. Between the holidays and projects, things are a bit hectic at UDL. Could you provide Sue and

I with a status on the Actavis Warning Letter? I know you were going out there to audit Actavis and that was part of the agenda. Otherwise, how did you -- excuse me -- how did you find their operation? Thank you and take care."

MR. KAPLAN: And that's dated?

THE WITNESS: That is dated on the 12/7/06.

BY MR. COVENY:

Q. He responded back to you. Now, for the record, it says, "Can you provide sue and I." Would that be Sue Powers?

A. Sue Powers, yes.

Q. Okay. On this one here you were obviously concerned a bit about the warning letter that's on it?

A. Yes, um-hum.

Q. Okay. And as you've testified, you went through Charles Koon on most situations to remedy that.

Could you summarize his response to that? If you familiarize yourself again with that e-mail, did he consider Actavis to have responded appropriately to that? Was he satisfied with their response?

MR. TABER: Objection; the document speaks for itself.

MR. COVENY: Okay.

MR. KAPLAN: It calls for hearsay.

BY MR. COVENY:

Q. In his response, again, looking at that document, he indicates, "Overall Amide/Actavis is having lots of problems and is also trying to integrate with their new owners, Actavis." He indicates that they did not do a systems audit. And he says, "I don't think they could handle one right now."

In your discussions with Chuck Koon, is it fair to say that it appears that Actavis was overwhelmed at this time with the FDA warning letters that had come in?

MR. KAPLAN: Objection; calls for speculation.

BY MR. COVENY:

Q. From your -- why did you inquire with Chuck why the progress of the warning -- the progress Actavis was making with the warning letter?

A. In order to obtain -- it was one of our monitoring processes. In order to obtain more

information, we would have gone through Chuck to see if we could obtain any more information.

Q. Okay. And at this time we've already looked at your summary of the warning letters. But at this time were you starting to be concerned with Actavis as a supplier?

A. I was -- I was very confident within our processes and procedures that we have in place that everything that we were releasing was within our -- the specifications for the product.

Q. And what was the basis of that confidence?

A. Knowing the systems that we have in place when we bring product in and our -- all of our quality system checks.

Q. Would that include your independent testing of the product?

A. Yes.

Q. Did you conduct that independent testing on premise?

A. No.

Q. Could you tell us how that independent testing was done?

A. It would have been sent out to one of

our outside contract laboratories. We do not have a laboratory at UDL.

Q. Okay. Is Salay one of the --

A. Celsus?

Q. Is it Celsus?

A. Yes.

Q. Okay. One of the ones that you would regularly use --

A. Yes.

Q. -- to test product?

Were there others?

A. To test this product I believe at the time it was Celsus. We do have another contract laboratory, but I believe it was Celsus.

Q. And based on their testing of the product, you were confident that the product you were distributing was -- met standards?

A. It met the requirements of our stability program that it met the USP criteria for potency and dissolution.

Q. Okay. If you wouldn't mind at the very top of that, would you mind just reading that very short e-mail you sent back to Chuck in response?

A. "Thank you for the update. In view of

your findings, is Mylan having any second thoughts on Digitek? That would impact UDL as well since we unit dose that product. Any insight you could provide would be helpful."

Q. Okay. In your under -- did check indicate in your recollection, Mr. Chuck Koon, that Mylan was having second thoughts about Digitek at this time?

A. I don't recall getting a response back from Chuck other than the document that I'm looking at.

Q. Okay. I'll go ahead and put up another e-mail here then. This one here will be No. 55. Here are copies. This begins with Bates No. 211109. And it is Chuck's response, Chuck Koon's response there.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M55, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. And are you with me on there?

A. Yes, okay.

Q. Okay. Would you mind reading that one as a way to refresh your memory?

A. His response?
Q. Yes.
A. Okay. "I couldn't speak as to second thoughts, but we are definitely going to keep close tabs on the situation at Amide. I've briefed our quality management, and I don't think any new actions have been taken but rather than -- excuse me -- rather we want to stay in close contact with Amide and perform much more extensive release than we did previously."
Q. Okay. What is a -- what is a release? What is he referring to when he says "perform much more extensive releases"?
A. This would be Mylan's release of the product, and I can't speak to that. I'm not familiar with what they do to release the product.
Q. At UDL do you have any authority or influence over third-party vendors on -- with over which ones you use?
A. It is my responsibility to provide information with the compliance status of the company, and I give that information to management.
Q. And who specifically in management to you give that to?

A. Right now it would be my direct report which is Jodi Eichelberger.

Q. Okay. How long has Ms. Eichelberger been in that position?

A. Approximately two years.

Q. And do you know who -- who you would have sent that to prior to her?

A. Prior to that would have been Vince Mancinelli.

Q. Vince Mancinelli on our -- let me have that organizational chart.

Executive vice president and general manager of UDL Laboratories?

A. Correct.

Q. Is he no longer in that position?

A. He is no longer in that position.

Q. Okay. All right. Did you have any discussions with anyone concerning dropping Actavis as a supplier of Digitek?

A. Dropping Actavis? I don't recall having any conversation along that line.

Q. Okay. Why then did you -- did you ask Chuck Koon if they were having second thoughts? Was it your understanding that they might be

considering moving away from Actavis as a supplier of Digitek?

A. I would have kept in close contact with Mylan since they were the supplier of the product, they are a subsidiary of ours, so that I could pass that information on to our management.

Q. Would it be fair to say that you deferred to Mylan, Mylan's decision as to whether or not to distribute product made at Actavis?

A. If Mylan were to make that decision, we would not be purchasing that product since it came directly from Actavis. So, it would have impacted --

MR. KAPLAN: From Actavis to Mylan.

BY THE WITNESS:

A. From Actavis to Mylan and then it would come to UDL, so we could not have been getting that product directly from Actavis. So anything that Mylan -- any decision that Mylan would do would impact -- would impact our company as well.

BY MR. COVENY:

Q. Okay. If -- is it fair to say then that if Mylan continues to carry and distribute that product that you would continue to distribute it

for Mylan?

A. I would say yes because I'm -- I am confident with the processes and procedures we have in place to release product to ensure it meets its specifications.

Q. Have you ever recommended to management that a distributor or supplier be dropped that you no longer purchase product or distribute product for them?

A. Be dropped?

Q. Be dropped, let me rephrase that.

A. Okay.

Q. Have you ever recommended to management that the product from a certain manufacturer no longer be distributed or that it was unsafe to be distributed?

A. That wouldn't have been my decision on my own, but I don't recall ever expressing that to management.

Q. Okay. These e-mails, the feel of the e-mails is that you referred -- you deferred to Chuck Koon in terms of his assessment of what was happening at Actavis? Is that a fair assessment?

A. Could you rephrase that question?

Q. Yes. Is it fair to take from these e-mails that you deferred to Chuck Koon's assessment of Actavis, that if he was happy with how things were going at Actavis, you were satisfied?

A. Chuck would have just been providing the information to us. That decision would not be made by Chuck alone, not to my knowledge. He would have been the -- my contact to obtain as much information as I could so that I could pass it on to management.

Q. Did you share Chuck's opinion that Actavis was having difficulties trying to integrate with their new owners that -- and Mylan was having difficulties integrating with its new owner Actavis and that that perhaps was some of the source of the problems?

MR. TABER: Same objection; document speaks for itself. It was not authored by her.

BY MR. COVENY:

Q. All right. Okay. I'm going to put up this next one which will be No. 56. This is a memorandum from yourself.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M56, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Could you tell us -- could you tell us what -- when you generated this document, approximately?

A. According to this date, September 16th, 2006.

Q. And, again, this was in response to the Actavis warning letter; is that correct?

A. Let me look. Yes.

MR. KAPLAN: When you say the warning letter, what are you -- which one are you talking about?

BY THE WITNESS:

A. The a warning letter. It says was issued August 15th, 2006. So that would have been what this is in reference to.

BY MR. COVENY:

Q. All right. Under "Findings" when you wrote this, you indicate, "Deviations demonstrating the firm's failure to comply with 21 CFR."

No. 1, could you read No. 1 to us?

A. Six potential serious and unexpected

ADEs dating back to 1999 for Digoxin."

Q. What is an ADE?

A. It is an adverse drug event.

Q. Okay. Could you read No. 2 to us?

A. Actually I didn't finish reading No. 1.

Q. Okay.

A. It says, "Submitted information was incomplete and/or inaccurate on some of the 15-day alert reports."

So, you wanted me to read No. 2?

Q. Yes.

A. Okay. "Serious and unexpected ADE reports were not promptly investigated. (Minimal case information on a fatality with no follow-up.)"

Q. Do you recall the specifics of that at all?

A. I'm not sure if that was relating to Digitek. I don't have enough information here in front of me. This is just a summary.

Q. But according to this there are at least six potentially serious and unexpected adverse events dating all of the way back to 1999 for Digoxin?

A. Um-hum, that were either incomplete or

inaccurate.

Q. Did this in any way lead you to wonder whether Mylan was having second thoughts about carrying Digitek from Actavis?

MR. TABER: Just note my objection because you are suggesting something to her that is not in that document. The fact that the ADEs were there is not why there was a citation. It was purely a matter of paperwork.

BY MR. COVENY:

Q. Let me reask the question then.

Having read the warning letters, was that the basis of your wondering whether or not Mylan was having second thoughts about carrying Digitek?

A. I'm unsure -- I'm not sure how to respond to that.

Q. Is it fair to say that you were at this time concerned about the Digitek product coming out of Actavis?

A. Again, I can only speak to our process and procedures, and I was very confident that anything that we released met -- was within its specification.

Q. Okay. Okay. Let's go ahead and put up an e-mail. Here you are. This would be No. 57.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M57, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. It is document No. 36659. Again, from Chuck Koon to yourself sent Thursday, January 10, 2008. It is 2006 responses.pdf.

I put this up because, again, Mr. Koon referring to in No. 2 there, he says, "Actavis is still on our radar. They are very difficult to deal with as I'm sure you know."

You indicated, I believe, earlier that you did not have a lot of direct contact with Amide or Actavis at this time, is that correct?

A. That is correct.

Q. Did you find contact with them difficult or of course -- or difficult to get information from them concerning the warning letter?

A. We went through Mylan to see if we could obtain the information.

Q. Okay. So, you didn't try -- you didn't try directly -- most of your efforts were --

A. Were through Mylan.
Q. -- were directed through Mylan?
A. That's correct.
Q. And it's your understanding then that Mylan was having a difficult time receiving that information?
A. According to what Chuck is stating, that's what he is stating in this document.
Q. And you wouldn't have any reason to doubt him?
A. No.
Q. Okay. This will be No. 58.
(WHEREUPON, a certain document was marked Deposition Exhibit No. M58, for identification, as of 1/26/10.)
BY MR. COVENY:
Q. Okay. Can you tell us what this is?
A. This is a reassessment summary of Actavis.
Q. Okay. And when did you produce this?
A. January 21, 2008.
Q. Okay. And why did you produce this? Do you --
A. This is part of our vendor assessment

program.

Q. Okay. And traditionally do you always do background information when you are producing one of these?

A. Background information is to just basically identify the company, our association with the company. That would be what the background is.

Q. And according to this document, how long had Actavis, and previously Amide, been producing -- or been providing Digitek? And according to this it says manufactured by Actavis but purchased through Mylan. How long had that relationship been going on?

A. Since 2004.

MR. KAPLAN: Chuck, do you want to take just a minute and write down your choice there and then we'll -- for lunch so I can turn it in.

(WHEREUPON, there was a short interruption.)

MR. KAPLAN: You can maybe turn off the camera for a minute so we can finish that.

THE VIDEOGRAPHER: We are off the record at 10:54 a.m.

(WHEREUPON, a recess was had from 10:54 to 11:00 a.m.)

THE VIDEOGRAPHER: We are back on the record at 11 o'clock a.m.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M59, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. All right. I'm going to go ahead and hand you an e-mail here, and this will be Exhibit M59.

Could you tell me who Cassandra Bird is?

A. Cassandra Bird is in quality assurance at Mylan Pharmaceutical.

Q. And could you tell me the date that this e-mail was sent?

A. April 25th, 2008.

Q. Okay. And would you go ahead and read the e-mail beginning "Actavis is issuing a recall."

A. Okay. "Actavis is issuing a recall on Digitek. We have placed the following materials on QA hold and are in the process of locating the remaining orders. No product on this list can ship from the D.C. to date. Yesterday was the last day

any outbound shipments can be recorded in the distribution history. In the event there are any invoicing issues to be corrected from yesterday's shipment that would result in a shipping day of today to be posted in the distribution history, please document accordingly and provide the information to Cass Bird in Morgantown. There should be no outbound shipments recorded after yesterday," and that would be 4 -- on 4/24.

Q. 2008?

A. 2008, yes.

Q. Okay. Would you tell me was this -- how were you originally notified of the recall, of this Digitek recall?

A. The -- originally?

Q. Yes.

A. Okay. I would have been notified by Cassandra Bird that there was a lot one lot in question and that UDL did not receive any of that lot. We did not repackage or distribute any of that lot. And then there would have been a follow-up at -- and I'm not exactly sure at what point. Cassandra would have notified UDL that the recall had expanded to all lots of Digitek.

Q. This particular e-mail here, to which does this refer, to the --

A. I -- I am not sure. This was not -- well, I was copied on this. As far as the timing, I can't speak to the timing. I'm not sure what the timing was.

Q. Approximately how much time do you recall when -- occurred between the time you were notified original -- when you first were notified that there was a problem with a particular lot and the time in which the general recall -- this recall was issued, do you recall how much time went by?

A. I don't.

Q. Okay. Was it a matter of days, months?

A. No, not months. It would have been more along the line of days.

Q. Okay. So, when this came through, it wasn't entirely unexpected?

A. I'm not sure what led up to this prior to.

Q. Okay. What was your role specifically when the recall was announced? Did you have any particular responsibilities?

A. Yes.

Q. Could you tell me what those were?
A. My responsibility is if there is a recall conducted that I would -- I would be the one that would issue the recall letter and that as far as coordinating the recall, that would be done in the -- coordinated between myself and Sue Powers and quality assurance.
Q. Had you conducted any recalls prior to this Digitek recall in your tenure in your current position?
A. Have we -- are you asking me if we've ever conducted a different --
Q. Had you had to do a recall prior to this one?
A. Yes.
Q. Okay. So this wasn't your first experience --
A. No.
Q. -- with a recall?
A. No.
Q. Had you done -- had you been tasked with doing recalls of the same magnitude prior to this one?
A. A Class 1 recall, no.

Q. So this was your first experience with a Class 1 --

A. With Class 1, yes.

Q. -- recall? Okay.

And you said that you and Sue Powers then worked together --

A. Correct.

Q. -- to initiate the recall?

But you had to assist in drafting the letter, the recall letter?

A. Yes.

Q. Okay. I'm going to pull that one down here and we'll go ahead and put that e-mail up, which is basically what you've just testified here. This will be No. 60. It is document No. 6050.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M60, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. In this e-mail to Sue Powers from yourself, you basically state what you just testified that you had to help draft the letter?

A. Right.

Q. Did Cassandra Bird -- and if this e-mail

refreshes your memory, did Cassandra Bird begin -- draft the letter for you at Mylan and you took that?

A. No. She drafted a letter for Mylan and then she sent that to me.

Q. Did you use that as a template then to draft your -- your letter?

A. It's possible. I'd have to compare the two letters, but it is very possible.

Q. It's fair to say you did not -- that Cassandra Bird was taking the lead position since she was from Mylan and that you got --

A. Yes.

Q. Okay.

A. Because UDL would have been notified by Mylan of the recall.

Q. Did you have a set procedure in place for engaging in a Class 1 recall?

A. We have a procedure in place for conducting -- if we get involved in a recall, we do have a procedure in place for recalls.

Q. Does that -- does that procedure have to be in accordance with any FDA regulations?

A. Yes.

Q. Okay. And that would be I assume then your job to make sure that the procedure complied with FDA --

A. Correct.

Q. -- regulations?

I know earlier you indicated that most of your training was on-the-job training.

A. Um-hum.

Q. How did you then come up -- come to understand the FDA requirements? Did you -- you didn't -- did you take any courses or any --

A. Training through seminars, this type of thing, review of CFR guidances, any things along that line.

Q. What are guidances?

A. FDA will put a guidance out, for example, a recall guidance. This is how you conduct a recall. So, there are guidances that they provide to industry that would give you their current thinking along the lines of how you should perform a function of some sort.

Q. And when you were first notified that this recall -- when you were notified that it would be a Class 1 recall, were you prepared to act

immediately or did you have to seek advice from the FDA or anybody to go forward with it?

A. We were prepared to act immediately on the recall because we have a system in place that would require us to put everything on hold. And then there would have been notification to our district that we would be involved in this recall.

Q. Okay. According to -- or when the recall first came out, at which time did you -- let me rephrase that.

At first you were told that there was simply one lot that was at question and you did not believe that UDL had any of that product, is that correct?

A. We knew for a fact that we didn't. We never received that lot.

Q. When the recall was expanded --

A. Yes.

Q. -- did you look simply for the lots that were listed in the recall and put those on a hold or did you put a hold on Digitek entirely?

A. We put a hold on Digitek entirely.

Q. I'm curious, why would you put a hold on the entire -- on the entire product when only

certain batches had been indicated for recall?

A. At the time we were notified that it extended to all lots of Digitek. So that would have impacted anything that we would have packaged and distributed.

Q. Okay. Did this impact any products other than Digitek that you received from Mylan that had been produced at Actavis?

A. This recall?

MR. TABER: Objection.

BY MR. COVENY:

Q. No. When this original recall came out --

A. Yes.

Q. -- did you put a hold on any other product that came from Actavis or did you limit it strictly to Digitek?

MR. TABER: Objection.

MR. COVENY: That doesn't mean she can't answer.

BY MR. COVENY:

Q. Did you specifically --

A. This recall -- this recall only involved Digitek.

Q. And that's the only product that in response to this recall you put on hold at that time?

A. Correct. That to the best of my knowledge, that is correct.

Q. Could you tell me who Steritype is?

A. Stericycle?

Q. Stericycle, yes.

A. Stericycle is the company that would have been contracted to conduct the Class 1 recall.

Q. And when you say "conduct the recall," what would you mean?

A. They would have sent the letters to -- it had to go to the consumer level. So they would have been -- they would have been -- we would have put them on contract to conduct that recall for us, to send the letters.

Q. And they were already retained prior to the recall. Were they part of your standard operating procedure?

A. No.

Q. Had they already been contracted with?

A. No.

Q. Okay. So you contacted them as a result

of the recall?

A. They would have been contacted as a result of the recall.

Q. But not by you?

A. No.

Q. Okay. Do you know who would have done that?

A. That would have been in coordination with Mylan who would have done the same thing. So, I'm not sure -- I'm not certain who -- who actually made the arrangements.

Q. But it was made at Mylan, to your knowledge?

A. To my knowledge. I don't know, but I believe so.

Q. Okay. This is an e-mail from Cassandra Bird. We'll put this one in as 61.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M61, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Let's see. You were copied on this one, I believe. Let's see here. I'm going to pull it off the screen just for a second to see if you were

copied on this one here.

A. No.

Q. Okay. Well, I'll go ahead and pull that one then. Let's see here. I'll leave it up there since I have it in. I'll just ask you a question.

This is an e-mail from Sandra Bird?

A. Um-hum.

MR. KAPLAN: It's Cassandra.

BY THE WITNESS:

A. Cassandra.

BY MR. COVENY:

Q. Cassandra. Thank you.

Does the FDA require that you keep in constant contact with them during a recall?

A. Could you define what you mean by "constant"?

Q. Absolutely. Did you have to report to the FDA the progress of the recall?

A. Yes. You have to send periodic status reports to the FDA.

Q. Okay. And that would have been your job?

A. Yes.

Q. Did you have to do it independently at

UDL or could Mylan make those responses?

A. No. We had -- we had to go through our distribute. They went through their district.

Q. All right. Are you familiar with the gold list?

A. The gold list?

Q. Yes, the customer gold list.

A. I'm not too familiar.

Q. All right. But did you provide a customer list then to Stericycle, a list of all of the customers you wanted them to contact?

A. Yes, yes.

Q. Would that have been UDL's responsibility to provide all contacts to Stericycle for issuance of recall letters?

A. If -- if they were contracted to conduct the recall, we would have had to provide them with a customer list.

Q. Okay. How quickly were you able to generate that list for Stericycle following the recall?

A. I don't know the timeline. I'm not sure.

Q. Okay. Do you recall how many notices

had to be sent out?

A. No, not to go to the consumer level, no.

Q. Compared to your previous recalls, was this -- was this a much more significant recall in terms of the numbers of people that needed to be contacted?

A. That -- it went to the consumer level, and that's what a Class 1 recall would do. So, being the first Class 1 recall I was involved in, this was -- this went to a larger customer base.

Q. Let me make sure -- yes, you were copied on this one here. I'm going to put up another e-mail from Cassandra Bird that you were -- dated May 8th of 2008. This will be No. 62, document No. 20272.

MR. KAPLAN: Do you have another one?

MR. COVENY: Sorry.

MR. KAPLAN: Do you have another one?

MR. COVENY: Yes. Let me put it up here on the screen for you. There you are.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M62, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. You were copied on this one along with many other people, so you may need just a moment. At the very bottom of the first page begins an e-mail. This is shortly after the recall is issued.

Did you at any time attempt to or need to contact Actavis to get information on the recall directly?

A. Myself personally, no.

Q. No. Mylan -- you got your information from Mylan, is that correct?

A. Yes.

Q. And it appears that what was -- Cassandra Bird, was she the person -- the point person at Mylan for the issuance of the recall?

A. Yes.

Q. Okay. And so you -- did you ever talk to Cassandra Bird concerning the recall yourself?

A. I may have. I don't remember back that far.

Q. She expresses in this e-mail repeated attempts to reach anyone in the quality unit of Actavis.

MR. TABER: Just objection. Are you

attributing that statement to Cassandra Bird?

MR. COVENY: To Cassandra Bird.

MR. TABER: I'm not sure that's an accurate, but go ahead.

BY MR. COVENY:

Q. Did Cassandra Bird or anyone at Mylan indicate to you at this time that -- how long they thought this recall process was going to take place?

A. No.

Q. Did you have an understanding at the inception of how long this process was going to take?

A. No.

Q. Who produced the return kits for consumers to send the products back? Did you have to produce those or did Stericycle?

A. Stericycle.

Q. Was -- okay. Did you have to -- did you have any involvement in making up those return letters or --

A. As in reviewing them?

Q. Yeah.

A. I don't recollect that.

Q. Okay. From the time that you first received notice that there was a Class 1 recall, how long did it take you to get letters issued to consumers?

A. I can't -- I can't provide you the exact timeline. I don't remember.

Q. Approximately was it -- did it take days, months?

MR. TABER: Objection.

BY MR. COVENY:

Q. Okay. Any recollection of how long it took before you got your first letters out?

A. I can't give you an exact timeline.

Q. Okay. Did any of the -- was any of the product, to your knowledge, sent directly back to UDL?

A. Not to my knowledge, no.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M63, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. This is an e-mail which we'll mark M63 from yourself to Val --

A. Schissel.

Q. -- Schissel. Who is Val Schissel?
A. Did you just ask me who she is?
Q. Yes.
A. Okay. She works in my department and she would have assisted in the coordination of the recall information.
Q. Okay. And when is this e-mail dated?
A. It's dated August 15th, 2008.
Q. Okay. Approximately four or five months after the issuance of the recall?
A. Um-hum.
Q. And the recall was still ongoing?
A. Yes.
Q. Okay. What is 100 percent effectiveness?
A. When -- depending on the classification of the recall, it will tell you what percentage of the original consignees, they call them consignees that were contacted, how many that you would have to contact to ensure, yes, they did receive the recall notification. That's all part of the process.
Q. Okay. And were you in charge of monitoring that process at UDL at all?

A. Are you asking me if we conducted that?
Q. Yes.
A. No. Stericycle.
Q. Okay. Did they report to you the progress?
A. Yes.
Q. Okay. And as of August, down towards the bottom of that page, "At this time we have 32,980 non-responders."
Who would be a non-responder?
A. Someone that did not send a form back saying, "Yes, we did receive it. No, we don't have product." I'm not -- without seeing the actual document that was sent to the customer, I can't really respond as to who would have been the non-respondent in this particular case.
Q. At what point in time were all products that were -- that had originated from Actavis put on hold for distribution?
MR. TABER: Objection; and I would remind you that Judge Goodwin has already ruled that discovery of products other than Digitek is not permissible. So, I would ask that you either withdraw your question or rephrase it in such a way that it

relates only to Digitek.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M64, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Okay. This one here will be Exhibit 64. This is from Howard Martin.

Do you know who Howard Martin is?

A. Howard Martin, I believe he is in customer service at Mylan.

Q. Okay. And you are copied, it looks like, on this next page, a document 593692.

Would you read your e-mail that you wrote on 7/21/2008 at the bottom of that page?

A. At the bottom of the page?

Q. Yes.

A. "We just received" --

MR. TABER: Note my objection again for the same purpose.

MR. COVENY: Okay.

MR. TABER: This is a document relating to something other than Digitek I assume?

MR. COVENY: I believe we have the part redacted that is of concern.

MR. TABER: So, where does it say Digitek?

MR. COVENY: We'll -- it's not that. We'll hold that one. We'll come back to it. We'll hold that one for later.

One minute until the end of the tape. All right. Let me do -- well, we are going to have -- we have one minute left until the end of the tape. I'll go ahead and get this document on and then we'll have to go ahead and change out tapes. This one here will be No. 64.

MR. KAPLAN: 5.

THE COURT REPORTER: 65.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M65, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. 65. There you are. There is yours. And if you'll go ahead and familiarize yourself with the document.

A. Okay.

Q. I believe we'll have to change tapes before we get to it, so we'll go off the record.

THE VIDEOGRAPHER: We are off the record at 11:24 a.m. with the end of Tape 1.

(WHEREUPON, a recess was had from 11:24 to 11:30 a.m.)

THE VIDEOGRAPHER: We are back on the record at 11:30 a.m. with the start of Tape 2.

BY MR. COVENY:

Q. All right. We are beginning with document M65, Bates No. 5805.

Are you familiar with this document?

A. This is a receiving -- a copy of a receiving document.

Q. Okay. Page 4 on this one here, the fourth page would be Bates No. 5808. I'll pop that up here.

What's the date on this document?

A. Down at the bottom.

Q. Okay.

A. It was verified on 6/29/07.

Q. Okay. And do you -- can you tell who verified that?

A. It looks like -- I can't remember her first name, but it's McClean. She is one of the QA receiving inspectors.

Q. Okay. Up about halfway up the page there it talks about containers sampled.

A. Right.
Q. How many?
A. Three bottles were sampled.
Q. And how many pills were there?
A. It said quantity sampled is 80 tablets.
Q. Okay. And then defects found?
A. It says four tablets out of UDL's thickness tolerance.
Q. Now, originally it said none, is that correct?
A. Um-hum.
Q. But that's crossed out. And can you see what's written next to that?
A. Yeah. That's Peggy Finch's initials and date when she crossed that out.
Q. Okay. So that was a -- so, can you tell me how that's done? It indicates none found and then she crossed that out and wrote in. Was none found by an original inspector and then when she verified it, any idea?
A. I don't know the details of why the -- for the reason for that strikeout.
Q. Okay. Was this batch then accepted?
A. Yes.

Q. And it was accepted notwithstanding that four tablets were out of UDL's thickness tolerance?

A. They were out of UDL's thickness tolerance, yes.

Q. Okay. Can you -- do you have any reason to -- or any explanation as to why it was accepted?

A. UDL would establish its specifications for the creation of the tooling which is tighter than what would be allowed, the range of the thickness from the manufacturer. So, it was within their range, but it was not within our range.

MR. KAPLAN: Lower or higher?

BY MR. COVENY:

Q. Okay. And which is something that we discussed earlier in the deposition that you have tighter standards --

A. Right.

Q. -- for size and for assay than do the --

A. Right.

Q. -- manufacturers?

A. Right.

Q. Okay.

MR. KAPLAN: Tell him whether it was higher -- lower or higher?

BY MR. COVENY:

Q. Is that correct?

A. But this actually -- these were actually smaller. These four tablets that they found were out of our tolerance, but they were smaller, not larger.

BY MR. COVENY:

Q. Is that indicated on there? I don't see that.

MR. KAPLAN: If you look at 5815, page 5815 you'll see the specs.

BY THE WITNESS:

A. You'll have an example of the actual. This is the actual --

MR. KAPLAN: And if you look at numbers --

MR. COVENY: Okay.

MR. KAPLAN: -- 3, 7, 8 and 11, you'll see that they are thinner than the UDL tolerance specs. The UDL tolerance specs, just for your information, are 3.15 millimeter to 3.29 millimeter. And you'll see that three of those four tablets were .01 or 1/100 of a millimeter smaller and one was .03 or 3/100 of a millimeter smaller, not larger, so, if that helps.

BY MR. COVENY:

Q. How much of your time would you say was -- well, all right. Let me rephrase that.

Was a significant portion of your -- of your daily work dedicated to the recall once it was announced?

A. Initially I would have had to spend some time making sure. There is more to it than just issuing a recall letter.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M66, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. This would be Exhibit No. M66. Do you know what this is? It's Bates No. 202796.

A. I believe this document was something that was requested through Mylan to document how much time we were spending on actual -- the recall as far as the ongoing paperwork associated with the recall.

Q. Did you keep time sheets?

A. Did we keep time sheets?

Q. Did you personally keep time sheets like this on your time spent on the recall?

A. I may have originally, but I don't remember what was -- what was on that, um-hum.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M67, for identification, as of 1/26/10.)

BY MR. COVENY:

Q. Okay. No. 67 here. An e-mail from yourself to Cassandra Bird.

Was Cassandra Bird the one that wanted to keep time sheets on people, the time spent on the recall?

A. Yeah, originally she would have sent that out saying that they wanted us all to keep record of any of the time that we would have spent on the recall.

Q. To your knowledge, do you know why she wanted to keep time sheets?

A. Are you asking me to what purpose were the time sheets?

Q. Yeah. Did she indicate why she wanted you to keep time sheets concerning all of the time you spent on the recall?

A. Not directly. I don't recall directly if she told me what they would be used for.

Q. Okay. Was UDL, to your knowledge, being reimbursed for the time employees were being spent -- spending on the recall?

A. I don't know the details of any of the reimbursement.

Q. Okay. But from this e-mail, is it fair to say that you did not keep a daily log of the hours that you spent on it?

A. At the time that I received this document, I wasn't aware that we were supposed to be keeping track of our time so that that's -- at that point forward I would have kept track of any time.

Q. So, for the first month and a half, you did not?

A. I didn't --

Q. Approximately.

A. Right.

Q. Okay. All right.

MR. COVENY: All right. At this time I do not have any further questions for you. It has been a pleasure. I believe counsel for one of the Plaintiffs, Michael, has a few questions if you wouldn't mind entertaining those.

Michael, do you want to sit here so you can have a microphone?

MR. COLEY: You know what, I've got one apparently.

MR. COVENY: Oh, you do.

EXAMINATION

BY MR. COLEY:

Q. Okay. Good morning, Ms. Radtke.

A. Good morning.

Q. My name is Michael Coley, and I represent several Plaintiffs in the Digitek action, Ms. Connie Quinn. I'm going to just have a few questions for you, just follow-up questions.

With regards to your training and background, you mentioned that you had no formal training after -- for the 25 years that you worked with -- that you've been with UDL?

A. You are asking if I've had any more formal training?

Q. Formal training, yes.

A. Define formal.

Q. Yes. What I mean, in terms of -- you mentioned that you had seminars, that you've attended seminars.

In the last five years have you attended seminars with regards to the -- strike that.

A. FDA type stuff?

Q. Let me back up. Let me understand this.

A. Okay.

Q. Apparently your current position -- for how long have you held that position?

A. This current position?

Q. Yes.

A. I would say probably 18 years.

Q. Oh, okay. So, it's fair to say that if I asked you your training with regard to your current position, in the last five years how many seminars have you attended?

A. I've probably -- I try to attend one a year, one FDA seminar a year. To give you an exact number of the seminars, I really don't know.

Q. Okay. And in the last 12 months, other than the FDA seminar, have you attended any other seminars?

A. Oh, I'm not sure because they've -- we've -- they've had some that were offered like webinar type things, so I'm really -- I'm not certain.

Q. Okay. And in the last five years, other than the FDA seminars, have you attended any other seminars?

A. I would have attended seminars. I just can't give you an exact number or tell you what the nature was.

Q. What would be your best estimate in the last year how many seminars other than the FDA seminar?

MR. KAPLAN: I would caution you not to guess or speculate. I think you said you can't give an exact number.

BY THE WITNESS:

A. Yeah, I can't -- I can't answer that. I'm sorry.

BY MR. COLEY:

Q. No, I'm not asking you to guess or speculate. What I'm asking is what would be your best estimate? Would it be less than five or would it be more than 100 in the last year?

A. Well, it won't be more than 100. I'm not sure. I'm sorry. I can't answer your question. I don't -- I can't give you an estimate. I don't know.

Q. So, you wouldn't know whether it would be 25 or 100 or closer to 5 or closer to 100?

A. It would probably be closer to 5 than it would be to 100.

Q. Okay. And the -- do you recall the nature of any of the other seminars, the webinars that you've attended?

A. No, not --

Q. Okay. How about in the last five years, do you have any -- do you remember any of the webinars that you -- that you attended in the last five years?

A. There might have been some seminars on like validation. I'm really -- I really -- I'm sorry. I can't answer your question.

Q. Okay. You mentioned earlier that part of your job was to take care of the stability program, and I didn't quite understand. What did you mean by that?

A. What is stability?

Q. Yes.

A. Okay. As -- as a repackager, we are responsible to ensure that the product meets its specifications, meaning assay and dissolution, it's

analytical testing, and that's what would be utilized to support an expiration date that we assign to our package.

Once we remove it, we put it into a unit dose blister, we are required to do analytical testing to ensure that our package meets all of its specifications through the expiry date. So we have an ongoing stability program that prior to it ever being marketed we would test the product, it would never go into commercial distribution, and that's what would be our basis for our expiration date and assignment, and then we would do a number of -- we are required to do one annually to continue to support the product in that container closure system.

Q. Okay. And your role in the stability process is -- stability program would be what?

A. The stability manager. He is the one that's responsible for coordinating the program and then he reports to me.

Q. Okay. With regards to the reporting process, I understand -- and I think it was clarified later on, but with regards to Jodi Eichelberry, she -- I'm understanding that she took

the place of?

A. Jodi Eichelberger took the place of Vince Mancinelli.

Q. Okay. Vince Mancinelli was a vice president as well?

A. Um-hum.

Q. Okay. Let's see if I can do this without butchering it too much.

What I -- apparently you testified that you could only get information through the Freedom of Information Act regarding -- with regards to attempting to find out what had happened with Actavis FDA inspections, is that correct?

MR. TABER: Objection.

MR. COLEY: She can answer.

BY THE WITNESS:

A. Would you rephrase your question?

BY MR. COLEY:

Q. What I'm understanding is that at some point you were attempting to find out basically more information with regards to the FDA inspections of Actavis, is that correct?

A. The freedom of information -- the information you are able to obtain through the

freedom of information isn't always updated. Sometimes it's not released. In cases of warning letters, they have to work through the FDA before they would re- -- you know, release it to the public domain. So, in this situation I may have asked to see if there were other options to obtain more information, but we would start with the freedom of information. That's part of our process.

Q. And with -- you mentioned that you had -- you had spoken with someone at Mylan about getting more information beyond --

A. Chuck, Chuck Koon.

Q. Chuck Koon?

A. Yes.

Q. And were you ever satisfied that you had gotten the information necessary to make your assessment or to find out the information that you were -- you were seeking?

A. I believe UDL did everything within our powers to obtain the information, and we were trying to obtain it through Mylan, and Chuck Koon would have been my contact point.

Q. And there were several letters. And I

don't have each of them, but apparently you were requesting information from Mr. Koon with regards to the Actavis warning letter.

A. Right.

Q. Other than the information that we would -- that's been discussed here so far, did you receive any other information with regards to the Actavis warning letter other than the information you received from the freedom of information and the e-mails that have been discussed here?

A. Any information, that's a very all inclusive statement. I don't -- I mean, all I know is that we -- we attempt to get the information through Mylan and it was either provided or it was not.

Q. And as you sit there, you have no recollection or understanding that you ever received any other information other than the information that's been discussed in the e-mails sent between you and Mr. Koon?

MR. KAPLAN: Well, I'm going to object. That's overly broad and not specific.

BY MR. COLEY:

Q. Can I get the answer now, if you can.

A. Well, I really can't answer that because that's a -- that's a very all inclusive type question. I don't know what you mean by "any information."

Q. Okay. That's fair.

A. Yeah.

Q. What I'm understanding is that you have the e-mails that are going back and forth.

A. Right.

Q. And apparently you are in a pretty vigorous attempt to get information.

A. Absolutely.

Q. Okay. Other than the information that you received in these -- the e-mails, do you have any recollection of receiving any further information that we haven't discussed in those e-mails?

A. No.

Q. Okay. You mentioned that Mylan engages in audits of third-party vendors.

Did UDL engage in any audits of third-party vendors?

A. Are you asking me if we ever have engaged in?

Q. Yes, yes.
A. We would have -- we could have participated in -- in audits.
Q. Okay. Did you participate in any audits with regards to Actavis or its predecessor Amide?
A. I'm really not sure if I had or I hadn't. It would have been early on if I had participated, so I don't really have a recollection.
Q. When you say "early on," early on in your career?
A. Career, um-hum.
Q. Okay. Referring to I believe it's Exhibit 52 and which it's stated that quality controls should have authority to fully investigate errors at the manufacturer, were you referring to quality control at UDL or quality control at Mylan?
MR. KAPLAN: Don't guess or speculate --
THE WITNESS: No.
MR. KAPLAN: -- about some document that's not in front of you.
BY THE WITNESS:
A. Could you pull the document?
BY MR. COLEY:

Q. Sure, if we can pull that Exhibit 52.
A. This one. And you're referring to?
Q. Yes, the statement that quality controls should have authority to fully investigate errors at the manufacturer.
A. It's on page 5?
Q. Yes.
A. Um-hum. This would have been in reference to a summary of Actavis'. This was a 483 that was issued to Actavis. So to answer your question, this would have been as a summary of what was issued to Actavis.
Q. And meaning that was referring to corrective -- that would be part of the corrective action is that quality control should have the authority to fully investigate errors at the manufacturer?
MR. TABER: Objection.
BY MR. COLEY:
Q. Maybe I'm misunderstanding.
Okay. So in my understanding, this was a recommendation from the FDA to Actavis?
A. This would have been an observation issued by the FDA to Actavis.

Q. To Actavis, okay.

Okay. The memorandum with -- regarding the warning letters -- letters summary to Actavis, you -- it was to file, that memorandum that you made was to file?

MR. KAPLAN: Are you referring to a certain exhibit?

MR. COLEY: Yeah. I'm sorry. I'm referring to Exhibit 56.

MR. KAPLAN: Okay. Let's let her have that in front of her.

MR. COLEY: I'm sorry. I believe that's Exhibit 55.

MR. KAPLAN: 55.

BY THE WITNESS:

A. Can you rephrase your question?

BY MR. COLEY:

Q. Yes. Let me withdraw that question. I'll ask you another question.

With regards to 50 -- Exhibit 55, apparently --

A. He wants 55. This is 56. Okay. Thank you. Oh, no. This is 56. Sorry.

Q. Okay. I'm sorry. I'm probably causing

the confusion.

A. I'm confused.

MR. KAPLAN: Are we on the same page?

THE WITNESS: Yes.

MR. COLEY: I believe it is 55.

MR. KAPLAN: 55.

BY MR. COLEY:

Q. Apparently in 55 it refers to much more extensive releases in 55?

A. Right.

Q. Okay. And can you explain what -- what was meant by that?

A. Chuck is responding -- and this pertains to Mylan's system for releasing product, and I really can't speak to that.

Q. I see. What was your understanding as to what was meant by more intensive releases?

MR. TABER: Objection.

BY THE WITNESS:

A. I -- I don't know.

MR. KAPLAN: I think it's been asked and answered.

THE WITNESS: Yeah.

BY THE WITNESS:

A. I think I answered that question. I'm not -- that is Mylan's releases, and I'm not familiar enough to address your question.

BY MR. COLEY:

Q. Okay. I see. Okay. Okay.

And do you know what the CROM Data Acquisition System is or I'm sorry, Total CROM Data Acquisition System?

A. CROM data system, no.

Q. Total CROM Data Acquisition System?

A. I'm sorry.

Q. No. That's fine. That's fine.

MR. COLEY: Okay. I believe that's all I have.

THE WITNESS: Okay.

MR. KAPLAN: Do you want to take a little break?

MR. TABER: Two-minute break.

MR. KAPLAN: Yes, let's take a two-minute break.

THE VIDEOGRAPHER: We are off the record at 11:55 a.m.

(WHEREUPON, a recess was had from 11:55 to 12:09 p.m.)

THE VIDEOGRAPHER: We are back on the record at 12:09 p.m.

EXAMINATION

BY MR. TABER:

Q. Ms. Radtke, my name is Ed Taber. I represent Actavis. I have just a few follow-up questions for you.

A. Okay.

Q. First I would like to hand you a document that we've listed as UDL No. 13716, and if I put this on the screen, tell me if you can see it okay.

A. I should be able to read it. It is a little out of focus, but I can -- I think I can read it. A little more. No. Oh, that's not bad.

MR. KAPLAN: That's pretty good.

BY THE WITNESS:

A. Yep, there you go.

BY MR. TABER:

Q. All right. First of all, is this a true and accurate copy of an e-mail exchange that you had back in 2006 with Mike Armstrong at UDL?

A. That's correct.

Q. Do you remember the chain of events that

led up to this particular e-mail exchange?

A. I don't remember the particulars, but I do remember asking Mike, he -- to -- he handles the complaints, to make sure that they are -- just to look into the file to see if there were any adverse events reported for Digitek.

Q. Okay. And let me lay a brief foundation for this document.

At UDL is there a process in place to receive and follow up on product complaints?

A. Yes.

Q. And potentially from whom may such complaints come in?

A. The complaints come in through -- they go through the customer relations for UDL that is -- resides at Mylan Pharms, and then if it were an adverse reaction that would impact any product relating to Mylan, it would go through PSRM, which is product safety -- I can never remember what that stands for, but it is management of product complaints. And anything under our label would be reported to UDL.

Q. All right. And so are there records kept of those product complaints or adverse event

reports?

A. Yes, we keep records.

Q. And looking then at this document, we're -- we're going to mark this in a moment.

MR. TABER: What number are we up to in exhibits?

THE COURT REPORTER: 68 is the next one.

MR. TABER: All right. We'll mark this as Deposition Exhibit M68 I believe is the system.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M68, for identification, as of 1/26/10.)

BY MR. TABER:

Q. Does it appear that Mr. Armstrong at your request went through those same records as it relates to Digoxin covering the years 1999 through September of 2006?

A. That's correct.

Q. And is 1999 about the time when UDL first began to distribute Digitek?

A. Oh, I don't remember when we started distributing Digitek.

Q. All right. For those -- for those seven years did Mr. Armstrong find a single product

complaint for Digoxin?

A. Are you talking about adverse reaction complaints?

Q. Yes, the ones that --

A. No. He found nothing.

Q. And he looked?

A. Yes, he did.

MR. COLEY: Objection, a late objection.

BY MR. TABER:

Q. And has Mr. Armstrong then go ahead -- did he go ahead and document his findings in this particular piece of paper to you?

A. Yes, he responded that there were no AE complaints for Digitek dating back to 1999.

Q. Okay. And tell me if I read this correctly. He states, "Li," that's you, Li Radtke?

A. Yeah. I go by Li.

Q. It says, "Li, I went back through 1999 and we have had no," and he has underlined no, "Product/AE complaints for Digoxin."

A. Correct.

Q. Did I read that correctly?

A. Yes, you did read that correctly.

Q. All right. Now, this e-mail was written

to you in September of 2006?

A. Correct.

Q. Okay. Between September of 2006 and the time of the Dig recall in April of 2008, did UDL -- UDL have any product complaints or AE complaints for Digoxin during those two years?

A. You are asking about the AE complaints?

Q. Yes, I am.

A. Yes, no, we did not have any AE complaints from that point to the time of the recall.

Q. And if you had, would you in your position know about it?

A. Yes.

Q. So then are you comfortable sort of confirming that not only between 1999 and 2006, but from 1999 and through April of 2008 there were no such complaints for Digitek?

A. That's correct.

MR. COLEY: Objection.

BY MR. TABER:

Q. Okay. And just because -- I apologize. Because the court reporter was coughing over, I'm sorry, your answer was --

A. Yes.
Q. Your answer was what?
A. Yes.
Q. Okay. And I believe I asked you this, but our exit -- our Exhibit 68 is an accurate copy of the e-mail from your e-mail then?
A. Yes.
Q. I see. Okay.
All right. Next I would like to ask you about a four-page document which I'll hand to counsel first and then hand to you. This is Bates numbered, and produced in discovery, UDL No. 4768 through 4771. And I'll give the gentlemen an opportunity to look at it first --
A. Okay.
Q. -- if you wouldn't mind.
MR. TABER: We can go off the record if you guys want to take more time. This is an awkward silence on the videotape.
MR. COLEY: Yeah, that's fine. We can go off the record.
MR. TABER: Off the record.
THE VIDEOGRAPHER: We are off the record at 12:17 p.m.

(WHEREUPON, a recess was had from 12:17 to 12:18 p.m.)

THE VIDEOGRAPHER: We are back on the record at 12:18 p.m.

BY MR. TABER:

Q. Ms. Radtke, I'm handing you the four pages we've discussed which is a document entitled "UDL Internal Investigation Record."

A. Okay.

Q. If you wouldn't mind, just take a moment and look through those four pages, and I believe it has your name at the fourth page of it.

MR. KAPLAN: Are you marking this as 69?

MR. TABER: (Nodding head.)

BY THE WITNESS:

A. Okay.

BY MR. TABER:

Q. Are you all set?

A. Um-hum.

MR. TABER: All right. We'll mark this as 69, please, all four pages, one exhibit.

(WHEREUPON, a certain document was marked Deposition Exhibit No. M69, for identification, as of 1/26/10.)

BY MR. TABER:

Q. First of all I'd like to just identify on the last page, Bates No. 4471. First of all, is that your signature at the bottom of that document?

A. It is.

Q. And you've dated that May 15th of 2008?

A. Of 2008, um-hum.

Q. All right. Was this a report that was prepared by you or for you?

A. It was -- I -- it was prepared and I reviewed it and approved the document.

Q. Okay. So you've seen this before?

A. Um-hum.

Q. I'd like to walk you through just a few specific items.

First of all, on the bottom of page 1, there is a list -- a category that says, "Attachments."

A. Right.

Q. For context, was this a report that was prepared in the immediate wake of the April 2008 Digitek recall?

A. That's -- that is correct.

Q. And as part of this report, did UDL

endeavor to determine if in fact they were in possession of any so-called double thick tablets?

A. That is correct.

Q. And as part of this investigation, were you involved in it?

A. Involved in the actual investigation?

Q. Or in the reviewing of the reports thereof?

A. Yes, I was involved in the reviewing.

Q. Okay. And in the first page it says various components to this report, does it not, at the bottom where it says, "Attachments"?

A. "Attachments," yes.

Q. And as part --

(WHEREUPON, there was a short interruption.)

MR. TABER: Let's go off the record.

THE VIDEOGRAPHER: We are off the record at 12:22 p.m.

(WHEREUPON, a recess was had from 12:22 to 12:23 p.m.)

THE VIDEOGRAPHER: We are back on the record at 12:23 p.m.

BY MR. TABER:

Q. Ms. Radtke, at the bottom of page 1 of this report, Exhibit M69, it indicates various attachments.

My question is, as a component of this investigation, did UDL and/or the people with whom it was working endeavor to review the complaint history for Digitek?

A. That is correct.

Q. And did UDL and/or its delegates also examine retained samples of Digitek tablets?

A. That is correct.

Q. And did your folks at UDL also review the stability testing records for Digitek?

A. Yes.

Q. Okay. On page 2, which I'm showing you now, was there a summary done of this investigation then?

A. Yes.

Q. All right. And beginning at the first paragraph, does this indicate some of the records of UDL that were reviewed in the course of this investigation?

A. That is correct.

Q. Okay. And it says here, "The QA

Receiving Product Inspection records were examined and all lots demonstrated tablet thickness measurements within UDL product specification tolerances."

Did I read that correctly?

A. Yes, you did.

Q. All right. And is that true?

A. Yeah, to the best of my knowledge from the records that were reviewed.

Q. And then the report goes on -- by the way, this is referring specifically to Digitek, true?

A. Correct.

Q. The report goes on to set forth those standards for thickness of the both 250 microgram and 125 microgram doses of Digitek, true?

A. True.

Q. And you testified earlier in your deposition that for various reasons UDL has even tighter specifications than the FDA requires, right?

A. Correct, tighter specification than the Actavis' specifications, yes.

Q. Right. And do you know one way or

another if Actavis' spec is the USP spec?

A. It is -- to the best of my knowledge, the USP does not determine the specification.

Q. Okay.

A. That is the -- within the ANDA or the approved new drug application.

Q. The abbreviated new drug application?

A. Yes, that they would submit and get approval to market the drug from the FDA.

Q. Right. So, when this report says that all lots, being lots of Digitek, demonstrated tablet thickness measurements within UDL product specification tolerances, that means that all of those lots are not only within Actavis' thickness measurements but also within the tighter UDL thickness parameters, true?

A. Correct.

Q. Okay. Now, UDL, as I understand it, takes Digitek tablets out of bottles and puts them into a blister pack?

A. That's correct.

Q. And is there only a limited space around the tablet within the blister pack available?

A. Yes.

Q. All right. So, the report in the next paragraph discusses maximum thicknesses for tablets. Do you see that?

A. Yes, um-hum.

Q. Is it your understanding that if a Digitek tablet was too large, it would not fit in UDL's blister pack package?

MR. COLEY: Objection.

BY THE WITNESS:

A. That would be my understanding.

BY MR. TABER:

Q. Okay. And is that understanding set forth in this report?

A. Yes.

Q. All right. And it states on the second full paragraph, "The depth of the blister tool is NMT 110 percent of the maximum tablet thickness."

And does that mean in layman's terms that if the Digitek tablet is more than 110 percent of UDL's thickness specification, there may be -- there will probably be a problem encountered in production?

A. That's correct.

MR. COVENY: Objection.

MR. KAPLAN: Objection.

BY MR. TABER:

Q. Moving down the page then where it has a new paragraph entitled, "Batch Record Documentation," did this report that was provided to you by UDL further go through then and review UDL's batch records on all of the lots of Digitek in question?

MR. COLEY: Objection.

BY THE WITNESS:

A. Yes.

BY MR. TABER:

Q. Now, it states in the third full paragraph -- third full sentence, sorry, in that paragraph under Batch Record Documentation, "The QA" -- by the way, QA is quality assurance?

A. Correct.

Q. "The QA In-Process Inspection records were examined for each lot and there were no machine issues or inspection observations related to tablet thickness. The lots meet all in-process and finished goods inspection acceptance criteria for product release."

A. That's correct.

Q. Is that a fancy way of saying the tablets were all the appropriate size?

MR. COLEY: Objection.

MR. COVENY: Objection.

BY THE WITNESS:

A. That -- that would -- that would indicate such, yes, that there was no document -- no record of a problem noted during the run.

BY MR. TABER:

Q. All right. By the way, did this report at any time reveal that UDL had received any so-called double thick tablets of Digitek?

MR. COVENY: Objection.

BY THE WITNESS:

A. There would have been no indication.

BY MR. TABER:

Q. All right. By the way, you've seen this report before today, haven't you?

A. Yes.

Q. Okay. And you know that nowhere in this report does it state that a so-called double thick Digitek tablet was ever received by UDL, true?

A. That is correct.

Q. All right. Finally then, the next

paragraph is entitled "Examination of Retain Samples." And is this yet a third way in which UDL went back after the recall and checked the quality of the Digitek tablets it had?

A. It would have -- yeah, that would have been a way of us checking the tablets, yes.

Q. Okay. And in this paragraph does it reference what would have occurred if the tablets were too thick?

MR. COVENY: Objection.

BY THE WITNESS:

A. Yes, it does.

BY MR. TABER:

Q. Okay. And it states that the "blister cavity sizes have minimal head space that would prevent tablets to be packaged with double thickness."

Is that your understanding of how the manufacturing process at UDL works?

MR. COLEY: Objection.

BY THE WITNESS:

A. That's correct.

BY MR. TABER:

Q. All right. It goes on to state, "If the

tablet thickness were to exceed the blister cavity size during packaging, visible damage to the blister package would occur and the equipment would experience a seal station overload (jamming within the seal station) that would result in a breakdown of equipment -- of the equipment."

A. It would shut down, um-hum.

MR. KAPLAN: Shut down.

BY THE WITNESS:

A. Shut down.

BY MR. TABER:

Q. So, in layman's terms, if double thick tablets were received at UDL, they would shut down the equipment?

MR. COLEY: Objection.

MR. COVENY: Objection.

BY THE WITNESS:

A. That is correct.

BY MR. TABER:

Q. All right. And from what you know of this report and from your personal knowledge working at UDL, that never happened with Digitek, true?

A. No. That is true.

Q. All right. And records are kept that would reveal such a problem if it had occurred, true?

A. That is correct.

Q. Okay. And based on those records, it states in the very next sentence, "As stated above, there was no documentation in the batch record of a machine or inspection related issues involving tablet thickness."

True?

A. Correct.

Q. And that's accurate?

A. Correct. To the best of my knowledge, that's accurate.

Q. And finally, retain samples were actually physically measured, both 250 microgram tablets and 125 micrograms, and were determined to be within UDL's tolerances, correct?

A. That's correct.

Q. All right. And just to wrap it up, you also discussed complaint history, and the third page of the report sets forth what you said before, if I'm correct, which is that based on a review of product complaints prior to the recall, there were

no complaints as to the thickness or double thick tablets of Digitek, true?

A. That is correct.

Q. Okay. And then this is the very last page of this exhibit where you already authenticated your signature.

And finally, there is a reference here to the investigation summary, and it has a section entitled "Stability Records History."

A. Yes.

Q. And based on this paragraph, could you explain exactly what this means to us as it relates to UDL's review of its stability testing program for Digitek?

A. We would have examined all of the records of any of the stability, the analytical data that was generated, to continue to ensure that it met all of its specifications and that it was within the defined specifications of the USP, and we found -- we found no evidence that there was an issue or problem.

Q. All right. And by the way, this stability testing is something that is done on pretty much every lot of Digitek that comes to UDL?

A. No, no.
Q. Or is done periodically?
A. It's done -- yeah, one -- a random lot is pulled each year to continue to support the stability program.
Q. Okay. And so, appropriate and periodic sampling of Digitek tablets is done by UDL not just in the wake of the recall but in an ongoing basis?
A. Correct.
MR. COVENY: Objection.
BY MR. TABER:
Q. And the end result of the review of those records going back in time long before the recall was that there was no out of specification Digitek, true?
MR. COVENY: Objection.
BY THE WITNESS:
A. That is correct.
MR. TABER: Okay. I have no further questions. Thank you.
MR. KAPLAN: No questions.
MR. COLEY: No further questions.
MR. ARNOLD: No questions.
MR. COVENY: No questions.

MR. KAPLAN: Okay. We are complete.

THE VIDEOGRAPHER: We are off the record at 12:35 p.m. This concludes the videotape deposition of Liana Radtke.

(Time Noted: 12:35 p.m.)

FURTHER DEPONENT SAITH NOT.

STATE OF ILLINOIS)
) SS:
COUNTY OF K A N E)

I, JULIANA F. ZAJICEK, C.S.R. No. 84-2604, a Notary Public within and for the County of Kane, State of Illinois, and a Certified Shorthand Reporter of said state, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true record of the testimony given and the proceedings had;

That the said deposition was taken before me at the time and place specified;

That the reading and signing by the witness of the deposition transcript was agreed upon as stated herein;

That I am not a relative or employee or attorney or counsel, nor a relative or employee of

such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

IN WITNESS WHEREOF, I do hereunto set my hand this 3rd of February, 2009.

JULIANA F. ZAJICEK, C.S.R. No. 84-2604
Notary Public, DuPage County, Illinois.
My commission expires August 30, 2010.

I N D E X

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E X H I B I T S

E X H I B I T S (Continued)

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS: MDL NO.
LIABILITY LITIGATION : 1968

(This document relates to all cases.)

I hereby certify that I have read the foregoing transcript of my deposition given at the time and place aforesaid, consisting of Pages 1 to 145, inclusive, and I do again subscribe and make oath that the same is a true, correct and complete transcript of my deposition so given as aforesaid, and includes changes, if any, so made by me.

LIANA RADTKE

SUBSCRIBED AND SWORN TO
before me this day
of , A.D. 200 .

Notary Public

DEPOSITION ERRATA SHEET

Assignment No. 23029

Case Caption: Digitek MDL

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and Except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of _____, 20___.

_____

LIANA RADTKE

DEPOSITION ERRATA SHEET

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LIANA RADTKE

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LIANA RADTKE